

# Exhibit 1

1 ROBERT W. FERGUSON  
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10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
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NO. 1:23-cv-03026

DECLARATION OF  
SUSAN E. BIRCH

1 I, Susan E. Birch, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am the Director of the Washington State Health Care Authority  
5 (HCA) who oversees efforts to transform the health care system, helping ensure  
6 Washington residents have access to better health and better care at a lower cost.

7 3. HCA is the designated single state agency responsible for  
8 administering Washington's Medicaid program. HCA operates Apple Health,  
9 Washington State's Medicaid program. Apple Health provides free or low-cost  
10 health care for income-qualified individuals.

11 4. People who move to Washington with the intent to live here have  
12 access to Apple Health with no waiting period, if they meet the income eligibility  
13 requirements. A person does not need to live in the state for a specific period of  
14 time prior to applying for or receiving Apple Health coverage.

15 5. Washington State funds medication abortions for Apple Health  
16 clients in need of that health care. Unlike most other health care services provided  
17 through the Medicaid program, Washington receives no reimbursement for any  
18 portion of the cost of abortion services from the federal government. Washington  
19 State pays the entire cost of medication abortions provided through Apple Health.

20 6. Data available to the Health Care Authority suggest that between  
21 state fiscal years 2015 and 2022, Apple Health clients received over 32,000  
22

1 medication abortions. The average cost to Washington State of each of those  
2 medication abortions provided to Apple Health clients was about \$340.

3 7. Washington State also funds surgical abortions for Apple Health  
4 clients who need that health care. These services are also entirely funded by the  
5 State with no federal match.

6 8. Based on available data, the Health Care Authority has seen an  
7 average 5% year-over-year decrease between state fiscal years 2015 and 2022 in  
8 the number of patients receiving surgical abortion care in Washington State  
9 through Apple Health.

10 9. Data available to the Health Care Authority suggest that between  
11 state fiscal years 2015 and 2022, Apple Health clients received over 42,000  
12 surgical abortions. The average cost to Washington State of each of those surgical  
13 abortions provided to Apple Health clients was about \$610.

14 10. Any limits on the availability of medication abortion in Washington  
15 State is highly likely to cause an increase in the rate of surgical abortion for Apple  
16 Health insureds. The corresponding increase in costs resulting from the more-  
17 expensive surgical procedure would be borne by Washington State. I anticipate  
18 these increased rates of surgical abortion if there are barriers to access based on  
19 drug availability, limits on who may prescribe abortion medication, restrictions  
20 on where prescriptions may be filled, or other obstacles to patients' access to  
21 care.



1           11.     The Health Care Authority also oversees the School Employee  
2     Benefits Board (SEBB) and the Public Employees Benefits Board (PEBB) which  
3     develop benefit plans, including health care coverage, for eligible public and  
4     school employees, retirees, and dependents.

5           12.     The Health Care Authority has seen that between state fiscal years  
6     2017 and 2022 PEBB members received over 1,100 medication abortions;  
7     between fiscal years 2021 and 2022 SEBB members received over 250  
8     medication abortions. The average cost to Washington State of each medication  
9     abortion provided to PEBB and SEBB members ranges between \$510 and \$650.

10          13.     The Health Care Authority has seen an average 3% year-over-year  
11     decrease between state fiscal years 2017 and 2022 in the number of members  
12     seeking surgical abortion care in Washington State through the PEBB Program.

13          14.     The Health Care Authority has seen that between state fiscal years  
14     2017 and 2022 PEBB members received over 800 surgical abortions; between  
15     fiscal years 2021 and 2022 SEBB members received over 150 surgical abortions.  
16     The average cost to Washington State of each surgical abortion provided to PEBB  
17     and SEBB members was approximately \$1,500.

18          15.     Apple Health, SEBB, and PEBB also cover insureds who require  
19     management of pregnancy loss and miscarriage. I am aware that the same drugs  
20     prescribed for elective medication abortions are also prescribed to treat patients  
21     experiencing pregnancy loss. Just as with medication abortion, I anticipate  
22

1 increased rates of surgery to manage pregnancy loss if there are barriers to  
2 accessing the currently used drug regimen.

3 16. Although difficult to quantify with precision, there is no question  
4 that the cost impacts to the State of Washington from any further restriction of  
5 the availability of abortion medication would be significant. In the Apple Health  
6 Program alone, for example, assuming each of the 32,000 medication abortions  
7 between 2015 and 2022 had been surgical abortions, the resulting increased cost  
8 to the State would have been more than \$8.6 million dollars. In the PEBB and  
9 SEBB programs, assuming each of the 1,350 medication abortions between fiscal  
10 years 2017 and 2022 had been surgical abortions, the resulting increased costs to  
11 the State could have been more than \$1 million.

12 17. A decrease in the availability of mifepristone would also likely lead  
13 to increased costs to the State related to maternity care and childbirth, since a  
14 decrease in the availability or effectiveness of medication abortion is likely to  
15 lead to an increase in unwanted pregnancies being carried to term by insureds of  
16 Apple Health, SEBB, and PEBB.

17 18. In fiscal year 2021, on average for each delivery, the State paid  
18 about \$11,200 for prenatal care and delivery for Apple Health clients.  
19

20 I declare under penalty of perjury under the laws of the State of  
21  
22

1 Washington and the United States of America that the foregoing is true and  
2 correct.

3 DATED this 21 day of February, 2023, at [Olympia], [WA].

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6 Susan E. Birch  
7 Director  
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# Exhibit 2

1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
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EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

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15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
CONNIE CANTRELL

1 I, Connie Cantrell, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am the Executive Director of Cedar River Clinics, an organization  
5 that provides direct patient services, including birth control and abortion, and  
6 works to preserve and ensure access to reproductive and sexual healthcare. As  
7 Executive Director, I am responsible for an organization with four clinic locations  
8 and a telemedicine program in Washington State. I have served in this role since  
9 2017. Before that, I spent about a decade as Cedar River Clinic's Director of  
10 Operations and served for approximately 14 years as a Clinic Manager in Cedar  
11 River's Yakima clinic. I have also held the role of Certified Health Assistant, and  
12 Surgical Tech, and briefly served as a volunteer when I first joined Cedar River  
13 Clinics in 1992. All told, I have been with Cedar River Clinics for more than  
14 thirty years.

15 3. Early in my career at Cedar River Clinics, I received training as a  
16 Certified Health Care Assistant. I worked under the supervision of Attending  
17 Physicians to provide direct patient care for patients seeking abortions, including  
18 providing patient counseling, pre and post abortion care, and assisting in abortion  
19 procedures. I am also familiar with medication abortions.

20 4. Cedar River Clinics has locations in Renton, Seattle, Tacoma, and  
21 Yakima. Our reproductive health care clinics offer first and second trimester  
22

1 abortions, birth control, STI testing and treatment, cancer screenings, annual  
2 exams, and more. We have a LGBTQ wellness program which includes gender  
3 affirming care for transgender/non-binary patients. We offer both in-clinic and  
4 telemedicine services and are a member of the Reproductive and Sexual Health  
5 Program with the Washington Department of Health.

6 5. Cedar River Clinic was founded in Yakima in 1979 with subsequent  
7 locations being added when provider owners retired or wanted to close.  
8 Expanding abortion access is one of our priorities but we had to make the difficult  
9 decision to close our Yakima clinic in 2010. However, after hearing from patients  
10 traveling to us from Eastern Washington about the increasing wait times, we did  
11 a community needs assessment which led to our decision to reopen our Yakima  
12 location. Due to COVID, we expedited to begin our reopening as a telemedicine  
13 satellite site and last year, we opened for in-person care. Due to the reversal of  
14 *Roe v. Wade*, we expedited the plans to further expand the clinical space in  
15 Yakima so we can reopened fully to offer abortion procedures in March of 2023.

16 6. When the Yakima clinic resumes providing surgical abortions in  
17 March 2023, it will be only one of a small handful of full-service abortion clinics  
18 in Eastern Washington.

19 **The Impact of Dobbs**

20 7. For nearly 45 years, Cedar River Clinics had been providing first  
21 and second trimester abortion to individuals from across Washington State and  
22

1 those traveling from out of state or internationally. Many of those patients had  
2 to travel due to restrictive laws. Since the *Dobbs v. Jackson Women's Health*  
3 *Organization* decision in June 2022 and subsequent abortion bans, Cedar River  
4 Clinics are experiencing a rising tide in the volume of individuals coming to  
5 Washington from other states to seek an abortion. It is not limited to our region;  
6 we are serving patients from across the country especially the South and Midwest  
7 who are being impacted by the abortion bans in their states.

8 8. Based on my own and my staff's observation, in the post-*Dobbs*  
9 landscape, it has also been harder for individuals to understand their options when  
10 seeking abortion care. There is significant confusion among individuals,  
11 especially individuals traveling to Washington from states criminalizing abortion  
12 or restricting abortion access, regarding what is legal and what consequences they  
13 may face in their home jurisdiction. At Cedar River Clinics, we make it a priority  
14 to educate patients and inform them of their rights. Because of *Dobbs* we are  
15 seeing an increasing need to devote resources to patient education, reassurance,  
16 and outreach.

17 9. We have also seen an escalation in protesters since *Dobbs*. This  
18 includes protesters blocking patients from driving up to our clinics and harassing  
19 staff, patients, and their support people at the clinic entrance. In addition to the  
20 mental and emotional burden this imposes, this means clinics need to devote  
21 more resources to managing this issue and provide security.  
22



1     **The Importance of Mifepristone**

2           10. Mifepristone is one of a two-drug regimen that is the standard of  
3     care for medication abortions and miscarriage management. Medication  
4     abortions have become increasingly prevalent in Washington in the last several  
5     years. Cedar River Clinics offers medication abortion in-clinic and through  
6     telemedicine. Today, medication abortions make up approximately 40% of all the  
7     abortions Cedar River Clinics perform.

8           11. If mifepristone is removed from the market, it will have a  
9     devastating impact on individuals trying to access abortion. If patients are unable  
10    to access mifepristone, their options may only be a misoprostol-only abortion or  
11    surgical abortion. Returning to a one-drug, misoprostol-only protocol for  
12    medication abortion and miscarriage management will harm patients.  
13    Misoprostol is less effective and has more severe side effects. Moreover,  
14    misoprostol-only abortions typically require more doses over a longer period of  
15    time, and thus take longer to complete than abortions using a combination of  
16    mifepristone and misoprostol.

17          12. Surgical abortion will be the other option for patients who do not  
18    have access to mifepristone. There are a multitude of reasons why a patient may  
19    prefer a medication abortion to surgery including personal preference and matters  
20    of privacy and safety. Medication abortion offers greater privacy for patients,  
21    some of whom may fear being seen by community members or by an abuser if  
22

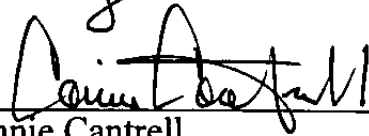
1 forced to visit a known abortion clinic. Patients often prefer not to face protesters.  
2 Other individuals may not have the ability to travel to a clinic location for a  
3 variety of reasons, including being unable to take time away from work, childcare  
4 concerns, or to afford the cost of transportation. Although we subsidize care and  
5 abortion funds help as much as possible, the cost of surgical abortion is also  
6 prohibitive for many patients.

7 13. Clinics would also very likely see a higher number of second  
8 trimester surgical abortion cases if mifepristone is removed from the market.  
9 Arranging time off work, arranging childcare, and making travel plans for a  
10 surgical abortion takes time and could push some abortions into the second  
11 trimester.

12 14. For clinics themselves, surgical abortions require more time, money,  
13 and resources for staff, and to subsidize patient care. This means clinics would  
14 serve fewer individuals and abortion would become less accessible for all.

15  
16 I declare under penalty of perjury under the laws of the State of  
17 Washington and the United States of America that the foregoing is true and  
18 correct.

19 DATED this 21 day of February, 2023, at Seattle, WA.

20   
21 \_\_\_\_\_  
22 Connie Cantrell

# Exhibit 3

1 ELLEN F. ROSENBLUM  
Attorney General  
2 SANDER MARCUS HULL WSBA #35986  
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3 YOUNGWOO JOH, OSB # 164105\*  
Assistant Attorney General  
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7 Attorneys for State of Oregon

8 *\*Application for pro hac vice admission forthcoming*

9  
10 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

11 STATE OF WASHINGTON *et al.*,

12 Plaintiffs,

13 v.

14 UNITED STATES FOOD AND  
DRUG ADMINISTRATION;  
15 ROBERT M. CALIFF, in his official  
capacity as Commissioner of Food  
and Drugs; UNITED STATES  
16 DEPARTMENT OF HEALTH AND  
HUMAN SERVICES; and XAVIER  
17 BECERRA, in his official capacity as  
Secretary of the Department of  
18 Health and Human Services,

19 Defendants.  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
ALYSSA COLWILL, M.D.,  
M.C.R.

DECLARATION OF  
ALYSSA COLWILL, M.D., M.C.R.

1

Department of Justice  
1162 Court Street NE  
Salem, OR 97301-4096  
(503) 947-4700 / Fax: (503) 947-4791

1 I, Alyssa Colwill, hereby declare:

2 1. I am over the age of 18, am competent to testify as to the matters in  
3 this declaration, and make this declaration based on my personal knowledge.

4 2. I make this declaration in support of Plaintiffs' Motion for  
5 Preliminary Injunction.

6 3. I received my Doctor of Medicine from the Chicago Medical  
7 School at Rosalind Franklin University of Medicine and Science in 2012. I  
8 completed my residency in Obstetrics and Gynecology at the Hospital of the  
9 University of Pennsylvania in 2016. From 2016 to 2018, I was a Family  
10 Planning Fellow at the Oregon Health & Science University, and in 2018 I  
11 received a Masters of Clinical Research from OHSU.

12 4. Since completing my fellowship, I am an Assistant Professor in the  
13 Department of Obstetrics and Gynecology at OHSU. I am also board-certified  
14 by the American Board of Obstetrics and Gynecology, with a sub-specialization  
15 in Complex Family Planning. I am currently the Clinical Lead for the Complex  
16 Family Planning division at OHSU.

17 5. I have been licensed to practice medicine in the State of Oregon  
18 since 2016, license no. MD176540. I have also been licensed to practice  
19 medicine in the State of Washington since 2022, license no. MD61311123.

20 6. I am currently a medical provider at OHSU, in the Department of  
21 Obstetrics and Gynecology. As part of OHSU's Complex Family Planning  
22

1 division, I regularly see patients who seek pregnancy-related healthcare on a  
2 regular basis, including those seeking miscarriage management and termination  
3 of pregnancy via medication or procedural abortions.

4 7. In a typical month, I see about 35 patients seeking miscarriage  
5 management care or medication or procedural abortion. In the course of my  
6 career, I have supervised about 3000 medication-based treatments for  
7 miscarriage management or abortion. Of that number, about three-quarters  
8 involved the prescription and use of mifepristone.

9 8. Attached as **Exhibit A** is a copy of my current curriculum vitae.

10 9. I am familiar with the drug mifepristone. I have personally  
11 administered mifepristone in several clinical trials. Mifepristone is one of a  
12 two-drug regimen prescribed for medication abortions and miscarriage  
13 management. The drug is also used for the purpose of inducing delivery in the  
14 event of a second- or third-trimester loss. It is also used for procedural abortions  
15 after the first trimester.

16 10. For gestation of up to 70 days, the standard of care for medication  
17 abortion involves one dose of mifepristone and one dose of misoprostol. A  
18 patient first takes mifepristone, which blocks the hormone progesterone, which  
19 is necessary to support the maintenance of a pregnancy. Between 24 and 48  
20 hours later, the patient takes misoprostol, which causes cramping and bleeding  
21 to expel the contents of the uterus.  
22

11. The use of mifepristone in combination with misoprostol is widely considered in the field of obstetrics and gynecology to be the gold standard for medical management of miscarriages and medication abortions. That has been the case since the early 2000s, when peer-reviewed studies demonstrated that the use of mifepristone and misoprostol together is both safer and more effective than the use of misoprostol alone.<sup>1</sup>

12. The prescription and use of mifepristone with misoprostol is the standard of care for medication abortion in the State of Oregon and has been since the early 2000's.<sup>2</sup> The use of mifepristone for miscarriage management became standard of care in 2019 after a randomized trial showed improved outcomes compared to using misoprostol alone.<sup>3</sup> In the past twenty years, nearly all medication abortions have been via the two-drug regimen of mifepristone and misoprostol.

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<sup>1</sup> Medication abortion up to 70 days of gestation. ACOG Practice Bulletin No. 225. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;136:e31-4.

<sup>2</sup> Medication abortion up to 70 days of gestation, *supra* n.1.

<sup>3</sup> Early pregnancy loss. ACOG Practice Bulletin No. 200. American College of Obstetricians and Gynecologists. Obstet Gynecol 2018;132:e197-207; Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone pretreatment for the medical management of early pregnancy loss. N Engl J Med 2018;378:2161–70.

1           13. Mifepristone is also used for procedural abortion and in obstetrical  
2 complications. Mifepristone is also used for Cushing's syndrome. However,  
3 innovation and treatment with mifepristone has been limited due to REMS  
4 restrictions.

5           14. Although misoprostol can be prescribed alone for miscarriage  
6 management or medication abortions, it requires more frequent doses, with  
7 increased undesirable patient side effects, including nausea, cramping, bleeding,  
8 and flu-like symptoms.

9           15. Mifepristone is one of a small number of medications that the FDA  
10 subjects to a Risk Evaluation and Mitigation Strategy (REMS). The REMS  
11 impose restrictions on how a drug may be prescribed and used.

12           16. REMS are typically applied to inherently dangerous drugs, such as  
13 opioids.

14           17. Mifepristone, however, is extremely safe. In fact, its safety and  
15 efficacy is well documented in medical literature. The FDA's own publications  
16 on mifepristone show that the drug is safe and effective, demonstrating no  
17 scientific basis for subjecting the drug to REMS restrictions.

18           18. The REMS for mifepristone require certifications for prescribers  
19 (such as providers) and pharmacies. It further requires that mifepristone be  
20 dispensed by or under the supervision of a certified prescriber, or by certified  
21 pharmacies for prescriptions issued by certified prescribers. The REMS also  
22



1 require the use of certification forms for the pharmacy and prescriber (or  
2 provider), as well as a patient-agreement form. It also requires the National  
3 Drug Code and lot number from each dispensed package of mifepristone be  
4 recorded in a patient's record.

5 19. Additionally, for a certified pharmacy to fulfill a prescription for  
6 mifepristone, that pharmacy must be registered with the mifepristone  
7 manufacturer as being in a prescription-fulfillment relationship with the specific  
8 provider. In other words, each individual provider must *separately* contact each  
9 individual pharmacy for that pharmacy to be allowed to fulfill the provider's  
10 prescription.

11 20. Those certification requirements are onerous and impede access to  
12 mifepristone without sound medical justification. For example, if a patient in  
13 rural Oregon obtains a mifepristone prescription from a certified provider, but  
14 that provider does not have a registered relationship with the patient's nearest  
15 certified pharmacy, that patient cannot fulfill their prescription at that pharmacy  
16 in person.

17 21. Although recent changes to FDA rules do allow the mailing of  
18 mifepristone, that does not meaningfully mitigate the reduced access caused by  
19 the mifepristone REMS. For one, I am not aware of any retail pharmacies that  
20 are yet certified by the FDA for mailing mifepristone. And second, the mailing  
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1 of important medication can add another two or three days to the time it takes  
2 for a patient to receive crucial and time-sensitive care.

3 22. Further, many rural providers do not have the volume of patient  
4 care to justify the onerous steps to register as a certified provider required by  
5 the mifepristone REMS. As a result, they frequently refer patients out to other  
6 providers, such as OHSU. In 2022, for example, I received referrals weekly  
7 from rural providers for miscarriage management or medication abortion. That  
8 means that the patient must see a second provider for something that, but for the  
9 mifepristone REMS, their original provider could have handled more  
10 expeditiously and safely.

11 23. In short, the mifepristone REMS effectively reduces the number of  
12 providers available to a patient without a medically sound reason for its  
13 imposition. In addition to reducing patient choice, it also increases the patient-  
14 load of the providers who are certified. That also increases the average wait  
15 time for healthcare for conditions in which time is of the essence.

16 24. Combined with the time needed to establish healthcare with a new  
17 provider, that can delay treatment or adversely affect patient health. For  
18 example, those time sensitive delays can prevent a patient from being eligible  
19 for a medication abortion, limiting the patient's option to a procedural abortion.  
20 A patient diagnosed with a miscarriage may end up having unpredictable  
21 bleeding while awaiting treatment. In addition, a patient is more likely to have  
22

1 an incomplete miscarriage and require further interventions while trying to  
2 obtain care.

3 25. In my experience, those delays do often contribute to patients  
4 losing healthcare options or experiencing adverse health effects.

5 26. The mifepristone REMS does not enhance patient safety, because  
6 its requirements are redundant with what healthcare providers already do. For  
7 example, the provider certification form requires the provider to certify that  
8 they can accurately date a pregnancy, diagnose an ectopic pregnancy, and treat  
9 complications that may arise or refer to someone who could. But medical  
10 providers qualified to provide a medication abortion are necessarily trained in  
11 pregnancy dating, ectopic risk factors, and care coordination.

12 27. The Patient Agreement Forms required by the REMS also can  
13 cause patient confusion and distress. For example, the form requires the patient  
14 to declare they “have decided to take mifepristone and misoprostol *to end my*  
15 *pregnancy.*” But mifepristone is not just used for medication abortion; it is also  
16 the standard of care for medically managing miscarriage. Second, the form  
17 requires the patient to declare they “will take the misoprostol tablets 24 to 48  
18 hours after I take mifepristone.” But emerging medical evidence suggests that  
19 misoprostol may sometimes be appropriately taken fewer than 24 hours after  
20 taking mifepristone, and sometimes even concurrently. Thus, for those patients  
21 whose doctors direct them to take misoprostol fewer than 24 hours after  
22

1 mifepristone, the Patient Agreement Form is contrary to their doctor's advice  
2 and may lead to confusion. And, as I noted above, the Patient Agreement Form  
3 can also cause additional patient stress as the form causes some to worry that  
4 the medication is actually more dangerous than it is. The Patient Agreement  
5 Form can also make counseling more difficult, especially in circumstances  
6 requiring a translator.

7 28. When patients in early pregnancy contact OHSU for miscarriage or  
8 abortion care, OHSU staff schedules them for either an in-person or telehealth  
9 consultation with a provider in the department of Obstetrics and Gynecology.  
10 For my consultations, I begin each visit by reviewing the patient's medical  
11 history and symptoms to determine what types of abortions for which the  
12 patient is eligible. I then discuss with the patient the risks, benefits, and  
13 alternatives for each kind of abortion care for which they are eligible (informed  
14 consent). Lastly, I answer any questions they have so that they are able to make  
15 an informed decision.

16 29. Those procedures are consistent with the training and direction I  
17 have received from OHSU's Department of Obstetrics and Gynecology.

18 30. If those patients are eligible for, and choose, a medication abortion,  
19 we proceed with the visit for that care.

20 31. I discuss the medication abortion process and discuss the Patient  
21 Agreement Form with the patient. After the patient answers my questions, I ask  
22

1 whether they consent to a medication abortion. If they do, I confirm that  
2 consent in their medical record and sign a paper consent form.

3 32. I then go over the instructions for how and when to take their  
4 medication, what the follow-up process is, what they should do if they  
5 experience any of the (very rare) serious complications associated with  
6 mifepristone or misoprostol, and I answer any additional questions they may  
7 have.

8 33. I am also required by the REMS to review and have the patient  
9 sign the Patient Agreement Form. The Patient Agreement Form is duplicative  
10 of the information contained in the FDA's Medication Guide, which is  
11 dispensed to the patient with the medication.

12 34. I also prescribe mifepristone (with misoprostol) to patients who are  
13 experiencing a miscarriage. Under the REMS, I am required to sign the same  
14 Patient Agreement Form as I am for patients receiving mifepristone for a  
15 medication abortion. That is confusing and often distressing for patients,  
16 because the form does not describe circumstances that apply to patients for  
17 miscarriage management.

18 35. I have had patients, who were already undergoing the traumatizing  
19 experience of a miscarriage, become deeply upset, confused, or distressed at  
20 having to sign a form about medication abortion.

1           36. I recently had a patient who was experiencing a miscarriage for a  
2 pregnancy that she very much wanted. I counseled her on the availability of  
3 mifepristone for miscarriage management. The patient was already dealing with  
4 the anguish of losing her pregnancy. Upon reviewing the Patient Agreement  
5 Form that she had to sign, the patient was emotionally distressed and deeply  
6 upset at the form's requirement that she attest that she was *deciding* to end her  
7 pregnancy that she had lost.

8           37. As with any other medical procedure, I discuss risks and benefits,  
9 explain the treatment, and obtain informed consent for the prescription of  
10 mifepristone for miscarriage management or medication abortion. The Patient  
11 Agreement Form is duplicative of that counseling.

12           38. In the consent-process alone, the additional paperwork and  
13 procedure required by the mifepristone REMS adds at least 2-3 minutes of  
14 required provider-time per patient. According to data collected by the Oregon  
15 Health Authority, 4,240 patients in 2021 obtained medication abortions. That  
16 amounts to approximately 140 to 210 provider hours spent in 2021 on a  
17 medically unjustified hurdle to mifepristone access—provider hours that could  
18 have been spent providing care to other patients. That does not account for the  
19 administrative costs in time and money to obtain certification and to register  
20 prescription-fulfillment relationships with mifepristone manufacturers.  
21  
22

1           39. With a conservative estimate about 30-minutes per patient visit,  
2 that is an additional 280 to 420 patients who could have been provided  
3 healthcare in 2021. That additional patient capacity would certainly have been  
4 appreciated, as healthcare demand across the state exceeds providers'  
5 availability. At OHSU's Department of Obstetrics and Gynecology alone, there  
6 is a six-month waiting period for new patients.

7           40. Attached as **Exhibit B** is a copy of the OHA data describing the  
8 4,240 patients who obtained medication abortions in 2021. Notably, because  
9 those statistics are for only induced termination of pregnancies, they do not  
10 include cases of miscarriage management in which a non-viable pregnancy was  
11 diagnosed. Nor do they account for a significant portion of other circumstances  
12 in which a provider would need to review the mifepristone Patient Agreement  
13 Form with a patient. Thus, the above estimates almost certainly significantly  
14 underestimate the amount of provider time spent by Oregon providers on the  
15 REMS requirements in 2021.

16           41. The 2023 changes to the REMS requirements do not change the  
17 above time estimates, because they continue to require the same Patient  
18 Agreement Form.

19           42. To my knowledge, not one of my patients has experienced a fatal  
20 infection or death caused by mifepristone prescribed for miscarriage  
21 management or medication abortion. It is among the safest drugs I prescribe.  
22

43. Based on my experience, professional judgment, and the best available medical science, mifepristone is significantly safer than, for example, acetaminophen and Viagra, neither of which have any REMS restrictions. Acetaminophen toxicity is the second most common cause of liver transplant worldwide and is responsible for 65,000 emergency department visits, 2,600 hospitalizations, and 500 deaths per year in the United States.<sup>4</sup> Reports to the FDA have shown that Viagra was associated with 522 deaths after 13 months on the market.<sup>5</sup> In comparison, mifepristone has been associated with 28 deaths out of 5.6 million medication abortion cases from September 2000 to June 2022.<sup>6</sup>

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<sup>4</sup> Agrawal S, Khazaeni B. Acetaminophen Toxicity. [Updated 2022 Aug 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK441917/>.

<sup>5</sup> Al Ibrahim AH, Ghallab KQ, Alhumaid FI, Almahfoudh HH, Almadan AJ, Al Eid MA, AlMishqab MH, Alsaffar MF, Aljamea JH. A Systematic Review of Sildenafil Mortality Through the Years. Cureus. 2022 Dec 4;14(12):e32179. doi: 10.7759/cureus.32179. PMID: 36474651; PMCID: PMC9719720.

<sup>6</sup> U.S. Food and Drug Administration. Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022. Available at: <https://www.fda.gov/media/164331/download>.



1           44. In sum, the REMS restrictions on mifepristone are not medically  
2 justified, they impose additional burdens and stresses on patients, and they  
3 reduce access to essential reproductive healthcare, especially for those living in  
4 rural areas or with limited access to healthcare services.

5  
6 **I declare under penalty of perjury that the foregoing is true and correct.**

7  
8 EXECUTED on February 23, 2023.

9 *Alyssa Colwill, MD, MCR*

Alyssa Colwill, MD, MCR (Feb 23, 2023 15:44 PST)

10 Alyssa Colwill, M.D., M.C.R.

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DECLARATION OF  
ALYSSA COLWILL, M.D., M.C.R.

# EXHIBIT A

**CURRICULUM VITAE  
OREGON HEALTH & SCIENCE UNIVERSITY**

<b>NAME</b>	<b>Alyssa Covelli Colwill</b>	<b>DATE</b>	<b>2/16/2023</b>
-------------	-------------------------------	-------------	------------------

**I. PRESENT POSITION AND ADDRESS**

<b>Academic Rank:</b>	Assistant Professor
<b>Department/Division:</b>	Obstetrics and Gynecology
<b>Professional Address:</b>	3181 SW Sam Jackson Park Road UHN 50 Portland, Oregon 97239
<b>E-Mail Address:</b>	colwill@ohsu.edu

**II. EDUCATION**

**Undergraduate and Graduate (Include Year, Degree, and Institution):**

September 2004 – May 2008	University of Minnesota – Twin Cities Major: Bachelor of Science in Nutritional Science; Minor: Biology, Music Summa Cum Laude, Dean's List, High Distinction
---------------------------	---

**Postgraduate (Include Year, Degree, and Institution):**

August 2008 – June 2012	<u>Doctor of Medicine, M.D.</u> Rosalind Franklin University of Medicine and Science – Chicago Medical School
June 2012 – June 2016	<u>Internship &amp; Residency</u> Hospital of the University of Pennsylvania Obstetrics and Gynecology
March 2015	<u>Clinical Elective</u> Botswana UPenn Partnership Gaborone, Botswana, Africa
July 2016 – June 2018	<u>Family Planning Fellowship</u> Oregon Health & Science University
July 2016 – June 2018	<u>Masters of Clinical Research, M.C.R.</u> Oregon Health & Science University
September/November 2017, April 2018	<u>Clinical Elective</u> Kampot & Phnom Pehn, Cambodia, Asia

**Certification (Include Board, Number, Date, and Recertification):**

American Board of Obstetrics and Gynecology - Board Certified 11/12/19 (Exp 12/31/23)  
American Board of Obstetrics and Gynecology, Complex Family Planning Subspecialist – Board Certified  
7/25/2022

**Licenses (Include State, Date, Status, Number, and Renewal Date):**

March 29<sup>th</sup>, 2016 State of Oregon, Active Status, MD176540. Up to date with all renewals

August 4<sup>th</sup>, 2022 State of Washington, Active Status, MD61311123. Up to date with all renewals.

**III. PROFESSIONAL EXPERIENCE****Academic (Include Year, Position, and Institution):**

2016 – 2018 Instructor and Family Planning Fellow, Oregon Health & Science University

2016 – present Consultant Ob/Gyn for the Oregon Zoo

2018 – present Assistant Professor, Oregon Health & Science University

2021 – present Director of the Kenneth J. Ryan Residency Training Program

2022 – present Complex Family Planning Clinical Lead

**IV. SCHOLARSHIP**

**Area(s) of Research/Scholarly Interest: Family Planning with specific interests in analgesia for medical abortion, immediate postpartum intrauterine device placement, improving workflow utilizing implementation science, quality and safety, non-tubal ectopic pregnancies**

**Grants and Contracts:**

SFPRFSS20-18 (Colwill) 10/2020-9/2022

Society of Family Planning Research Fund \$114,693.06

Salary Support Grant

Role: PI

SFPRF17-16 (Colwill) 2/2017-6/2018

Society of Family Planning Research Fund \$91,020

Opioid Analgesia for Medical Abortion: A Randomized Controlled Trial

Role: PI

Foundation for Women & Girls with Blood Disorders (FWGBD) 2/2022 – exp 1/2023

Bleeding in Carriers of Hemophilia A: \$35,000

The Role of von Willebrand Factor, Platelet Function and Endometrial Tissue Expression of FVIII

Role: Co-Investigator

Ob/Gyn Mission Support Award (Colwill) 7/1/2022 – present

OHSU Ob/Gyn Department \$50,000

Oregon's Oasis: Creating a Visiting Residency Rotation for Ob/Gyn Residents Residing in Abortion Deserts

Role: PI

**Publications/Creative Work:**Peer-reviewed

Liberty, Abigail MD, MSPH; Samuelson Bannow, Bethany MD; Matteson, Kristen MD, MPH; Edelman, Alison MD, MPH; **Colwill, Alyssa MD, MCR**. Menstrual Technology Innovations and the Implications for Heavy Menstrual Bleeding. Obstetrics & Gynecology ():10.1097/AOG.0000000000005126, February 15, 2023. | DOI: 10.1097/AOG.0000000000005126

Liberty A, Nacev E, Doshi U, **Colwill AC**. Medical management of hepatic ectopic pregnancy with systemic methotrexate, MRI and serial HCG monitoring. J Case Rep Images Obstet Gynecol 2023;9(1):1-6.

Han L, Alton K, **Colwill AC**, Jensen J, McCrimmon S, Darney B. Willingness to Use Cannabis for Gynecological Conditions: A National Survey. *Journal of Women's Health*, Vol. 30, No. 3, March 2021: 438-444.

Reid JA, Bayer LL, Edelman AB, **Colwill AC**. Controversies in family planning: Management of cesarean-scar ectopic pregnancy. *Contraception*. 2020 Dec 23:S0010-7824(20)30459-5. doi: 10.1016/j.contraception.2020.12.006. Epub ahead of print. PMID: 33359510.

**Colwill AC**, Alton K, Bednarek P, Bayer L, Jensen J, Garg B, Beardsworth K, Edelman A. Cannabinoids for Pain Control during Medical Abortion: A Randomized Controlled Trial. *Obstet Gynecol*. 135(6):1289-1295, June 2020.

**Colwill AC**, Bayer L, Bednarek P, Garg B, Jensen J, Edelman A. Response to Letter. *Obstet Gynecol*. 135(6):1486, June 2020.

**Colwill AC**, Bayer L, Bednarek P, Garg B, Jensen J, Edelman A. Opioid Analgesia for Medical Abortion: A Randomized Controlled Trial. *Obstet Gynecol*. 134(6):1163-1170, December 2019.

Alton, K, Han, L, McCrimmon, S, Darney, B, **Colwill AC**, Jensen, J. Patterns of and Attitudes Towards Cannabis Use in Women's Health. *Obstet Gynecol*. 133:172, May 2019.

Lee DD, **Colwill AC**, Teel J, Srinivas SK. Safe passage: Improving the transition of care between triage and labor and delivery. *Quality Management in Health Care*. 2018 Oct/Dec; 27(4): 223-228.

**Colwill AC**, Schreiber CA, Sammel MD, Sonalkar S. Six-week Retention Rate of Immediate Post-placental Intrauterine Devices: A Retrospective Study of the Impact of Mode of Delivery. *Contraception*. 2018.

O'Rourke K, Teel J, Nicholls E, Lee DD, **Colwill AC**, Srinivas SK. Improving Staff Communication and Transitions of Care between Obstetric Triage and Labor and Delivery. *J Obstet Gynecol Neonatal Nurs* 2017.

#### Abstracts

**Colwill A**, Lee D, O'Rourke K, Romanos A, Teel J, Srinivas S. Improving handoffs between triage and labor and delivery at a university hospital: A pilot study. *BMJ Qual Saf* 24:736; 2015.

#### **Invited Lectures, Conference Presentations or Professorships:**

##### International and National

Six Week Retention of Intrauterine Devices Placed after Placental Delivery: A Retrospective Study. Poster Presentation at: American College of Obstetricians and Gynecologists Annual Meeting; May 16<sup>th</sup>, 2016; Washington, D.C.

Improving Handoffs Between Triage and Labor and Delivery at a University Hospital: A Pilot Study. Oral and Poster Presentation at: Institute for Healthcare Improvement; December 6-9<sup>th</sup>, 2015; Orlando, FL.

Opioid Analgesia for Medical Abortion: A Randomized Controlled Trial. PowerPoint Presentation at: Fellowship in Family Planning Annual Meeting; May 6<sup>th</sup>, 2017; San Diego, CA.

Is M&M Enough? Using Quality & Safety Strategies to Improve Patient-Centered Care. Powerpoint Presentation at the University of Hawaii; September 27<sup>th</sup>, 2017; Honolulu, HI.

Is M&M Enough? Using Quality & Safety Strategies to Improve Patient-Centered Care. Powerpoint Presentation at the Pacific Northwest Joint Family Planning Fellowship Symposium, University of British Columbia; February 2<sup>nd</sup>, 2018; Vancouver, British Columbia, Canada.

Laparoscopic Gravid Hysterectomy for Morbidly Adherent Placenta. Poster Presentation at American Society for Reproductive Medicine Scientific Congress and Expo, Virtual Congress; October 17<sup>th</sup>, 2020.

Mifepristone for Early Pregnancy Loss. Powerpoint Presentation for Vancouver Clinic Staff. March 3<sup>rd</sup>, 2021.

Dreaming of Wearing White Pants? Workup and Management of Abnormal Uterine Bleeding. Lecture at Contraceptive Technology, Virtual Meeting; September 24<sup>th</sup>, 2021.

Abortion Access: Crucial for Reducing Disparities in Maternal Mortality. 2021 Oregon Perinatal Collaborative Virtual Summit; October 15<sup>th</sup>, 2021.

Management of Heavy Menstrual Bleeding with Hematologic Disorders. Pacific Northwest Conference, Virtual Meeting; October 21<sup>st</sup>, 2021.

Dream of Wearing White Pants? Workup and Management of Heavy Menstrual Bleeding. Primary Care Review, Virtual Meeting; January, 2022.

Abortion Access: Crucial for Reducing Disparities in Maternal Mortality. Ob/Gyn Grand Rounds presentation at University of Washington. April 20<sup>th</sup>, 2022; Seattle, Washington.

Reproductive Healthcare Access: Crucial for Reducing Disparities in Maternal Mortality. Ob/Gyn Grand Rounds presentation at Creighton St Joseph's. May 13<sup>th</sup>, 2022; Phoenix, Arizona.

Allies for Equity Summit: Hunger and Reproductive Justice. Panelist. Hosted by the Oregon Food Bank. October 20<sup>th</sup>, 2022.

Comprehensive Reproductive Care in the Post-Roe Era. Pacific Northwest Update in Obstetrics & Gynecology. October 21<sup>st</sup>, 2022.

Abortion Access in a Post-Roe Environment. Oregon Perinatal Collaborative Summit, Virtual Meeting. October 28<sup>th</sup>, 2022.

#### Institutional

Second Trimester Abortion. Grand Rounds presentation at Oregon Health & Science University; September 29<sup>th</sup>, 2017; Portland, Oregon.

D&E Breakdown Barriers. Presentation to OR staff at Oregon Health & Science University; December 17, 2018; Portland, Oregon.

Abortion Access: Crucial for Reducing Disparities in Maternal Mortality. Family Medicine Grand Rounds presentation at Oregon Health & Science University. December 15<sup>th</sup>, 2021; Portland, Oregon.

OHSU Preparedness: The Impact of Upcoming Abortion Restrictions. Department of Medicine Grand Rounds at Oregon Health & Science University. June 21<sup>st</sup>, 2022; Portland, Oregon.

Reproductive Care in a Post-Roe Era. Department of Obstetrics & Gynecology Grand Rounds at Oregon Health & Science University. September 23<sup>rd</sup>, 2022; Portland, Oregon.

Abnormal Uterine Bleeding Evaluation and Treatment. Women's Health Hematology Consortium. Oregon Health & Science University. October 28<sup>th</sup>, 2022; Portland, Oregon.

#### Interviews:

What Americans Can Expect if Abortion Pills Become Their Only Safe Option. April 12<sup>th</sup>, 2022.

<https://fivethirtyeight.com/features/what-americans-can-expect-if-abortion-pills-become-their-only-safe-option/>

Changes to Abortion Laws Mean Ob-Gyns Have Less Opportunities to Learn Procedures. October 6<sup>th</sup>, 2022.

<https://www.npr.org/2022/10/06/1127307423/changes-to-abortion-laws-mean-ob-gyns-have-less-opportunities-to-learn-procedure>

OHSU Now: Visiting Resident to Receive Abortion Care Training. November 16<sup>th</sup>, 2022.

<https://news.ohsu.edu/2022/11/16/ohsu-welcomes-first-out-of-state-obgyn-resident-to-receive-training-in-abortion-care>

KGW8 Visiting Resident for Abortion Training November 16<sup>th</sup>-17<sup>th</sup>, 2022

<https://muckrack.com/broadcast/savedclips/view/l6J4wx1ira>

OHSU Now: OHSU study finds significant gaps in menstrual research and clinical care. February 15<sup>th</sup>, 2023.

<https://news.ohsu.edu/2023/02/15/ohsu-study-finds-significant-gaps-in-menstrual-research-and-clinical-care>

## V. SERVICE

### Membership in Professional Societies:

2020 – present FWGBD  
2016 – present Society of Family Planning  
2012 – present ACOG  
2012 – 2016 Obstetrical Society of Philadelphia

### Committees:

#### Departmental

2022 – present HASTE Reproductive Justice Committee Member  
2020 – 2021 HASTE Ally Committee Member  
2016 - present OHSU Gynecology Quality Education Committee Member  
2021 – present Chair of Clinical Competency for Complex Family Planning Fellowship

#### Institutional

2018 – present School of Medicine Faculty Council Committee Member

#### Workshops

5/2021: Intersectional Allyship for Racial Justice: A Workshop for White Allies (Equity in the Center)

## VI. TEACHING (OHSU Educators Portfolio)

### Classroom Teaching

Nurse-Midwifery Curriculum

“Contraception for Women with Chronic Medical Conditions” (November 2017)

Ob/Gyn Resident Quality and Safety Curriculum

“Using Quality & Safety Strategies to Improve Patient-Centered Care” (September 2017)

Ob/Gyn Resident Curriculum

“First Trimester Ultrasound” (August 2017, October 2017)

Third year medical student Ob/Gyn Clerkship curriculum

“Contraception” (April 2017, July 2017, August 2017, December 2017, February 2018, March 2018, April 2018, May 2018)

Physician Assistant Curriculum

“Ectopic and Other Early Pregnancy Risks” (April 2018)

“Contraception” (April 2017)

Medical Students for Choice LARC Training

“LARC Insertion Training” (October 2016)  
Quality and Safety Review  
“Gynecology Monthly Review and Quality Improvement” (October 2015, June 2016)  
“Obstetrics Monthly Review and Quality Improvement” (December 2015)  
“Gynecology Oncology Morbidity and Mortality Review” (January 2015)  
Maternal Mortality  
Botswana UPenn Partnership: Reviewing Maternal Morbidity (May 2015)  
IUD Insertion Training (March 2014)  
Methotrexate & Ovarian Reserve after Treatment of Ectopic Pregnancy (March 2014)  
Pain Management with IUD Insertion (July 2013)  
  
Nexplanon Trainer 2022- present

### **Curriculum Development**

Emergency Department D&C Policy update (6/2020)  
Family Planning Elective Medical Student Curriculum Development (6/2020)  
Nontubal Ectopic Pregnancy Guidelines (2019)  
Pregnancy of Unknown Location guidelines (2018)  
Fetal Burial Guidelines (2017)

### **Honors and Awards for Education and Service**

#### **Oregon Health & Science University**

##### Institutional

2020 OHSU Continuing Professional Development Clinical Star Award  
2018 Golden Rose Award

##### Departmental

2022 APGO Excellence in Medical Student Teaching Award  
2021 Resident Research Award Mentor  
2020 Gynecology Medical Student Educator Teaching Award  
2018 OHSU Fellow Teaching Award

#### **Hospital of the University of Pennsylvania**

##### Departmental

2014 Sharon Youcha, M.D. Compassionate Patient Care Award  
2013 Intern's Midwifery Award  
2012 Dean's Award, Gold Humanism in Medicine Honor Society Member

##### Institutional

2016 Penn Pearls Teaching Award, Resident Teaching Award for Excellence in Resident Education

#### **Rosalind Franklin University – Chicago Medical School**

2011 Medical Students for Choice Reproductive Health Externship Scholarship  
2010 Female Student Leadership Award



# EXHIBIT B

# Induced Termination of Pregnancy in Oregon, 2015-2021

1. Select a topic and year to display from the drop-down menus. Hover over any number or line for more information.
2. You can select a category to graph over time by clicking on a header or number in the table below. Hold Ctrl and click, or click and drag, to select more than one item. Click the item again to reset.

Select a topic:

Method of termination by length of gestation

Select a year:

2021

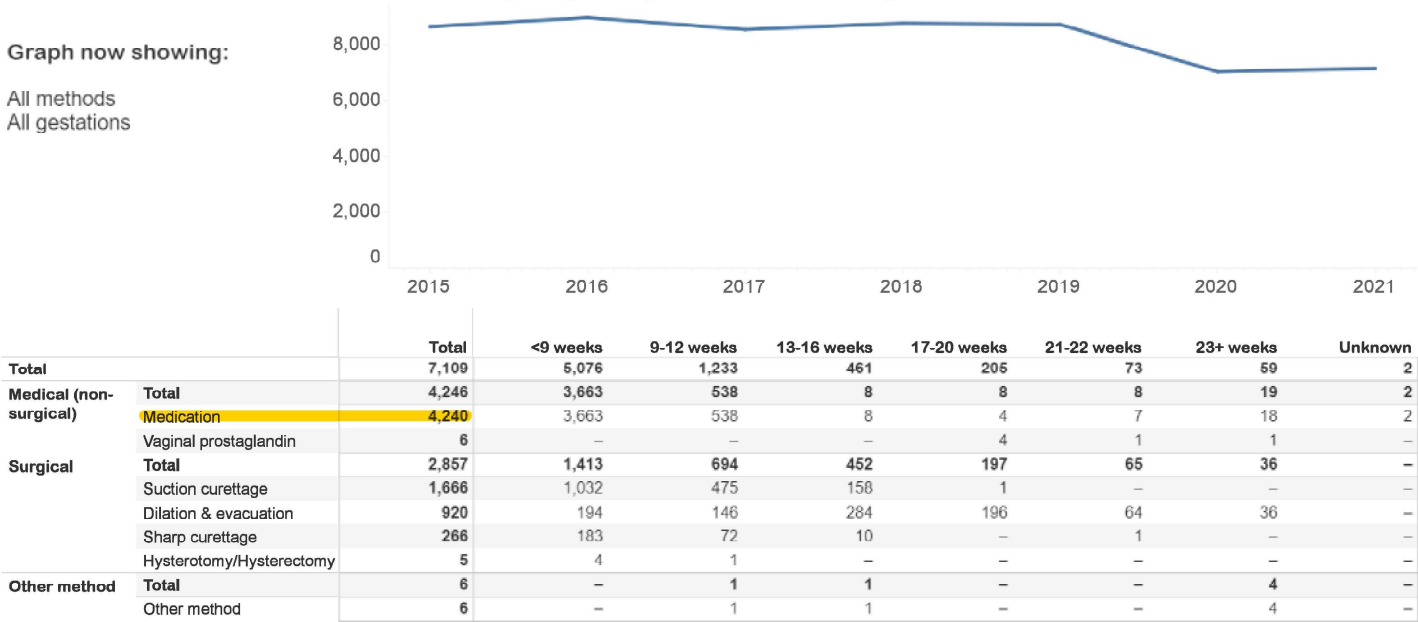
Total Oregon occurrence abortions

in 2021: 7,109



Navigate to historical counts and rates dashboard

Method of termination by length of gestation, 2021 Oregon occurrence abortions



Notes:  
A dash (-) means the quantity is zero.







# Declaration of Dr. Alyssa Colwill - 2.23.23

Final Audit Report

2023-02-23

Created:	2023-02-23
By:	Jason Lohman (jason.lohman@doj.state.or.us)
Status:	Signed
Transaction ID:	CBJCHBCAABAAcUQ2lxtD8zG7g5JdECIQoQs9S-vHZjnz

## "Declaration of Dr. Alyssa Colwill - 2.23.23" History

-  Document created by Jason Lohman (jason.lohman@doj.state.or.us)  
2023-02-23 - 11:36:06 PM GMT
-  Document emailed to colwill@ohsu.edu for signature  
2023-02-23 - 11:36:35 PM GMT
-  Email viewed by colwill@ohsu.edu  
2023-02-23 - 11:37:30 PM GMT
-  Signer colwill@ohsu.edu entered name at signing as Alyssa Colwill, MD, MCR  
2023-02-23 - 11:44:12 PM GMT
-  Document e-signed by Alyssa Colwill, MD, MCR (colwill@ohsu.edu)  
Signature Date: 2023-02-23 - 11:44:14 PM GMT - Time Source: server
-  Agreement completed.  
2023-02-23 - 11:44:14 PM GMT

# Exhibit 4

1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
Civil Rights Division Chief  
5 ANDREW R.W. HUGHES, WSBA #49515  
LAURYN K. FRAAS, WSBA #53238  
6 Assistant Attorneys General  
TERA M. HEINTZ, WSBA #54921  
7 (application for admission forthcoming)  
Deputy Solicitor General  
8 800 Fifth Avenue, Suite 2000  
Seattle, WA 98104-3188  
9 (206) 464-7744

10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
SUMONA DASGUPTA

1  
2 I, Sumona DasGupta, declare as follows:

3 1. I am over the age of 18, am competent to testify as to the matters  
4 herein, and make this declaration based on my personal knowledge.

5 2. I am the Director, Pharmacy Business & Strategic Development for  
6 the University of Washington (UW) Medical Center & Harborview Medical  
7 Center. I have held this position for a year. In this role, I oversee all business  
8 development in the pharmacy department across multiple hospitals including an  
9 academic medical center, level 1 trauma center, primary care network, and  
10 community hospital. This role oversees the 340B program,<sup>1</sup> expansion of  
11 pharmacy services through partnerships with stakeholders, and is focused on  
12 creating pharmacy programs that increase value to our patients. Prior to holding  
13 this position, I served as the Assistant Director for Pharmacy Audit and  
14 Compliance from 2013–2022. In that role, I oversaw all compliance functions in  
15 the pharmacy department, regulatory affairs including rule and legislation  
16 development and operational execution. Prior to joining UW Medicine, I served  
17 as the Compliance Officer for a public hospital district in King County, and as a  
18 \_\_\_\_\_

19 <sup>1</sup> Section 340B of the Public Health Service Act requires pharmaceutical  
20 manufacturers participating in Medicaid to sell outpatient drugs at discounted  
21 prices to health care organizations that care for many uninsured and low-income  
22 patients.

1 lawyer at K&L Gates in their healthcare practice with a focus on mergers and  
2 acquisitions. My credentials include a JD and a CHC (Certified in Healthcare  
3 Compliance), and I currently serve on the national board of 340B Health.

4 **UW Pharmacies**

5 3. UW Medicine currently has 11 outpatient pharmacies at its medical  
6 centers and clinics in Washington. In 2022, these pharmacies dispensed over  
7 600,000 prescriptions. In addition, UW Medicine also has inpatient pharmacies  
8 at the University of Washington Center – Montlake and Northwest, and  
9 Harborview Medical Center. The inpatient pharmacies provide pharmacist  
10 clinical services and drugs to patients at UW Medicine.

11 4. UW Medicine also has a mail order pharmacy system that is a  
12 URAC-accredited specialty pharmacy,<sup>2</sup> the Eastside Specialty Mail Order  
13 Pharmacy (ESC mail order pharmacy). This mail order pharmacy only supports  
14 UW Medicine patients, and prescriptions written by UW Medicine providers.

15 **The New Mifepristone REMS Requirement Requiring Certified Pharmacies**

16 5. I am familiar with the FDA's Risk Evaluation and Mitigation  
17 Strategy (REMS) on dispensing mifepristone, which was last modified on  
18 January 3, 2023 (2023 REMS).

19  
20  
21 <sup>2</sup> URAC is the nation's largest independent healthcare accreditation  
22 organization and establishes quality standards for the entire healthcare industry.

1           6. Under the 2023 REMS, mifepristone may only be dispensed by or  
2 under the supervision of a certified provider or by a certified pharmacy. The 2023  
3 REMS establishes an onerous certification process for pharmacies that choose to  
4 dispense mifepristone and imposes an array of requirements on certified  
5 pharmacies.

6           7. Certified pharmacies must designate an authorized representative to  
7 implement the certification process and ensure compliance and oversee the  
8 implementation with the 2023 REMS on behalf of the pharmacy.

9           8. The 2023 REMS imposes several obligations on certified  
10 pharmacies. For every mifepristone prescription it fills, a certified pharmacy must  
11 confirm that the prescriber is a certified prescriber by confirming that the  
12 requisite Prescriber Agreement Form is on file with the pharmacy or was received  
13 with the prescription. Failure by pharmacy staff to complete this verification  
14 could result in a citation against the pharmacy.

15           9. The 2023 REMS requires that the certified pharmacy can receive the  
16 Prescriber Agreement Forms by email and fax.

17           10. The 2023 REMS requires that mifepristone is delivered to the  
18 patient within 4 calendar days after the date the pharmacy receives the  
19 prescription. Complying with this deadline, requires the ESC mail order  
20 pharmacy to mail the prescription the next calendar day by 2pm to ensure it is  
21  
22



1 delivered in time. The pharmacy may be unable to meet this deadline if the  
2 Prescriber Agreement Form is delayed or not accompanied with the prescription.

3 11. If there is a delay beyond the 4 calendar days, the certified pharmacy  
4 must confirm with the prescriber the appropriateness of dispensing mifepristone,  
5 and document the prescriber's decision, which may delay the patient receiving  
6 the medication in a timely manner. Also, in the event of a drug shortage, this  
7 requirement could lead to significant delays. The requirement of delivery to the  
8 patient within 4 calendar days was not required in the prior REMS.

9 12. The 2023 REMS also requires pharmacies to record the National  
10 Drug Code (NDC) and lot number for each package of mifepristone dispensed.  
11 Information for the lot number is unique for each drug product and requires that  
12 the lot number be documented by an individual user in a free text field associated  
13 with dispensing the prescription. Without an IT system to automate this system,  
14 it makes compliance extremely difficult to guarantee.

15 13. Due to new restrictions under the 2023 REMS, we can no longer  
16 purchase mifepristone through our normal wholesalers. Consequently, the 2023  
17 REMS has necessitated the execution of new contracts, new accounts, and new  
18 purchase orders through a new wholesaler for the certified pharmacy to access  
19 the drug.

20 14. Under the 2023 REMS, UW pharmacies are required to track and  
21 report patient deaths to the prescriber, who must then notify GenBioPro, Inc. as  
22

1 required by the Prescriber Agreement Form. This is an unusual requirement—  
2 pharmacies do not typically have any role in ensuring that a prescriber notify a  
3 manufacturer about adverse events. Although deaths associated with  
4 mifepristone are extremely unlikely, the pharmacy has nonetheless had to  
5 develop a workflow to manage cases where it is notified of an associated death  
6 of a patient.

7 15. To date, my team has spent approximately 80 to 100 hours working  
8 on the implementation of the 2023 REMS. Implementation tasks have included  
9 developing new IT systems for dispensing mifepristone in compliance with the  
10 REMS, creating systems to manage the prescribing of mifepristone, creating  
11 electronic storage of Prescriber Agreement forms, training all pharmacy staff,  
12 designing a patient package, identifying new distribution channels from which to  
13 purchase the drug, and creating billing workflows specifically for insurance  
14 carriers that do not cover mifepristone.

15 16. Building out the infrastructure to implement the 2023 REMS has  
16 been very burdensome. We have had to create an entirely separate process for  
17 dispensing mifepristone. Without our sophisticated IT teams, I do not know how  
18 we would have managed implementation of these requirements. For smaller  
19 independent pharmacies or community hospitals with less sophisticated IT  
20 systems, the operational hurdles associated with the amended 2023 REMS may  
21 present insurmountable barriers to dispensing mifepristone.  
22

1           17. In addition to the work that has already been done to implement the  
2 2023 REMS, workgroups are still engaging in development, training and  
3 implementation. Additional pharmacy personnel involved in procuring,  
4 counseling, dispensing, handling mail orders, and auditing will all require  
5 training.

6           18. Implementing the 2023 REMS has been very costly for UW.  
7 Workgroup members have devoted long hours to implementation work.

8           19. The 2023 REMS also imposes additional audits on certified  
9 pharmacies, including one within six months of the first purchase of mifepristone  
10 and annually thereafter. All certified pharmacies are required to comply with  
11 audits carried out by the Mifepristone Sponsors or a third party acting on behalf  
12 of the Mifepristone Sponsors to ensure that all processes and procedures are in  
13 place and are being followed. A negative audit result can have a serious impact  
14 on a pharmacy and compromise its ability to continue dispensing mifepristone.  
15 These additional compliance requirements may also discourage smaller  
16 pharmacies from participating in the REMS program which means that patients  
17 will have fewer options to obtain mifepristone compared to other drugs.

18           20. I spoke with GenBioPro in December 2022 about the anticipated  
19 burdens the 2023 REMS would create. I shared UW's concerns about the  
20 Prescriber Agreement Forms and Certified Pharmacy Agreements and noted the  
21 potential for delays to patients resulting from the REMS. We also noted our  
22


1 concerns around auditing and explained that it would be difficult to ensure that  
2 all the requirements were met before dispensing the drug.

3 21. The 2023 REMS for mifepristone are different from other REMS  
4 that I have encountered. Typically, REMS are issued for a specific drug, rather  
5 than for a specific medical condition. Although we have seen some REMS that  
6 only apply to women, due to potential harms to a fetus, most REMS apply  
7 whenever a drug is dispensed. In contrast, the 2023 REMS for mifepristone is  
8 only applicable, based on the REMS materials, where the 200-milligram drug is  
9 being used for purposes of a medication abortion.

10 22. Mifepristone at 200 mg. is also used in UW clinics off-label as part  
11 of standard practice protocols for miscarriage management. The REMS  
12 materials, including the required agreements, refer only to the use of mifepristone  
13 for the purpose of terminating an intrauterine pregnancy, which can cause  
14 confusion when mifepristone is used for miscarriage management. The FDA has  
15 not indicated that it will exercise discretion enforcement under the REMS for use  
16 of mifepristone for miscarriage management. Consequently, providers need to  
17 review with their patients who have suffered a miscarriage a Patient Agreement  
18 Form stating that they have “decided to end a pregnancy.” Without clarity for  
19 when the REMS do and does not apply to the certified pharmacy, it will be  
20 difficult to ensure REMS compliance.

1 I declare under penalty of perjury under the laws of the State of  
2 Washington and the United States of America that the foregoing is true and  
3 correct.

4 DATED this 21 day of February, 2023, at Seattle,  
5 Washington.

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7 Sumona DasGupta  
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DECLARATION OF  
SUMONA DASGUPTA

# Exhibit 5

1 ROBERT W. FERGUSON  
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3 KRISTIN BENESKI, WSBA #45478  
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10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
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21  
22

NO. 1:23-cv-03026

DECLARATION OF PAUL  
DILLON IN SUPPORT OF  
MOTION FOR PRELIMINARY  
INJUNCTION

1 I, Paul Dillon, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am the Vice President for Public Affairs of Planned Parenthood of  
5 Greater Washington and Northern Idaho (PPGWNl). I have worked for PPGWNl  
6 since 2015, and have been in my current role since 2018.

7 3. In my role as Vice President of Public Affairs for PPGWNl, I am  
8 responsible for managing outreach in support of PPGWNl's mission to providing  
9 exceptional health care services, honest education and fearless advocacy. I  
10 represent PPGWNl in the communities we serve and within the affiliate as an  
11 executive leader.

12 **A. Access to Abortion in Washington**

13 4. PPGWNl operates 11 clinics throughout central and eastern  
14 Washington, with locations in Spokane, Spokane Valley, Pullman, Walla Walla,  
15 Moses Lake, Sunnyside, Pasco, Kennewick, Wenatchee, Yakima, and  
16 Ellensburg. Each clinic offers medication abortions. Procedural abortions are  
17 only available at our clinics in Spokane, Kennewick, and Yakima.

18 5. Washington has a strong legacy of protecting abortion rights. But  
19 rights aren't rights without access. In central and eastern Washington access to  
20 abortion is quite limited.



1           6. Of the 20 central and eastern Washington counties within  
2 PPGWNI's territory, only nine have abortion providers to my knowledge.<sup>1</sup>  
3 Because a majority of counties do not have abortion providers, and because those  
4 that do have only very few abortion providers, many pregnant people in central  
5 and eastern Washington have to travel a long way for medical care. For example,  
6 if someone lives in Republic, Washington, their nearest clinic providing abortion  
7 care is PPGWNI's clinic in Spokane, approximately three to three-and-a-half  
8 hours away.

9           7. PPGWNI's clinics are all located in medically underserved  
10 communities. PPGWNI sees a high percentage of patients on Medicaid. In central  
11 Washington in particular, PPGWNI serves a large population of monolingual  
12 Spanish-speakers, many of whom are migrant farmworkers. Access to abortion  
13 care is still very limited for these and other populations PPGWNI serves.

14 **B. The Impacts of *Dobbs***

15           8. The Supreme Court's *Dobbs* decision overturning *Roe v. Wade* has  
16 created significant barriers for PPGWNI's efforts to provide abortion care, even  
17 as abortion remains legal in Washington.

18  
19 \_\_\_\_\_  
20           <sup>1</sup>The 11 central and eastern Washington counties without abortion  
21 providers to my knowledge are: Klickitat, Okanogan, Douglas, Ferry, Stevens,  
22 Pend Oreille, Adams, Lincoln, Columbia, Garfield, and Asotin Counties.

1           9. With three of our clinics (Spokane, Spokane Valley, and Pullman)  
2 so close to the border, PPGWNI has long seen patients from Idaho. But since  
3 *Dobbs*, we have seen a significant increase in out-of-state patients.

4           10. In January 2023, PPGWNI saw an increase of 25% in total abortion  
5 patient visits compared to January 2022. We saw a 75% increase in Idaho patients  
6 from January 2023 compared to January 2022. This includes a 36% increase for  
7 procedural abortion patient visits and 90% increase for medication abortion visits  
8 from Idaho.

9           11. Our clinics in Pullman and Kennewick saw the biggest changes. In  
10 our Pullman clinic, we now have an outright majority of patients—53% in 2022  
11 and likely higher in 2023—coming from Idaho. This is up from 39% in 2021.

12           12. Further, with the closure of PPGWNI's Boise clinic, we have started  
13 to see an influx of out-of-state patients at our Kennewick and Walla Walla clinics.  
14 These clinics have not historically treated many out-of-state patients, but they are  
15 now the closest clinics for many people in southern Idaho.

16           13. Since *Dobbs*, We have also started to see patients come from as far  
17 away as Texas and Florida.

18           14. This increase in patient volume has led to longer wait times to see  
19 providers in PPGWNI's clinics including up to three weeks for smaller sites like  
20 Wenatchee and Walla Walla. These longer wait times can have serious  
21 repercussions because abortion is a time-sensitive service. In many cases, a  
22

1 three-week wait may put someone past the point where a medication abortion is  
2 possible.

3 **C. The Importance of Mifepristone**

4 15. As I noted above, all of PPGWNI's clinics provide medication  
5 abortions using mifepristone. Mifepristone is a very important medicine for  
6 PPGWNI's patients and providers.

7 16. Lack of access to mifepristone has negative consequences for  
8 patients seeking abortion as well as providers.

9 17. When patients are not able to access mifepristone, their options are  
10 misoprostol-only abortions or procedural abortions.

11 18. Based on many conversations with PPGWNI providers, I am aware  
12 that misoprostol-only medication abortions lead to more severe side-effects like  
13 bleeding, cramping, flu-like symptoms, and nausea. Moreover, misoprostol-only  
14 abortions typically require more doses of misoprostol over a longer period of  
15 time, and thus take longer to complete than mifepristone/misoprostol abortions.  
16 This means that a patient undergoing a misoprostol-only abortion is likely to  
17 spend additional days in discomfort and cramping until their abortion is complete.

18 19. Procedural abortion is the other option for patients who do not have  
19 access to mifepristone. For patients who, for whatever reason, are unable to  
20 obtain mifepristone within the first 10 weeks of pregnancy, procedural abortion  
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1 may be their only option. While procedural abortion is extremely safe and  
2 effective, it has several disadvantages compared to medication abortions.

3 20. Unlike mifepristone, which is available at each of PPGWNI's  
4 11 clinics, including via telehealth appointments, and can be mailed to patients  
5 in Washington, PPGWNI can only provide procedural abortions at three of its  
6 locations. Consequently, patients who need procedural abortions, but live far  
7 away from PPGWNI's clinics that provide it, may face significant travel barriers.  
8 And due to the lesser availability, patients requiring procedural abortions  
9 generally face longer wait times for appointments, which can lead to significant  
10 stress and other complications.

11 21. Procedural abortion is also considerably more expensive—both for  
12 PPGWNI and patients. Medication abortion costs \$700. For procedural care, if  
13 gestation is 19 weeks to 21 weeks, the cost can range between \$1,450–\$1,850.  
14 Beyond the cost of the procedure itself, patients undergoing procedural abortions  
15 often have to pay for things like travel and lodging, neither of which is necessary  
16 for a patient who simply receives mifepristone in the mail.

17 22. Furthermore, medication abortions are simply preferable to many  
18 patients. A patient undergoing a procedural abortion must come into the clinic,  
19 undergo a medical procedure, spend time in the recovery room, etc. By contrast,  
20 a patient undergoing a medication abortion can be in the comfort and safety of  
21  
22

1 home, in a supportive environment, with Netflix and a heating pad, if they so  
2 choose.

3 **D. The 2023 Mifepristone REMS**

4 23. While we were grateful for the removal of the in-person requirement  
5 with the FDA's recent updates to REMS for mifepristone, it still created an  
6 unnecessary pharmacy certification requirement that it does not impose for other,  
7 equally or less safe, medications. This creates additional barriers to access for  
8 patients who are travelling to our health centers from out of state and need  
9 time-sensitive care. Unfortunately, the updated REMS also retains longstanding  
10 requirements that providers be specially certified in order to prescribe  
11 mifepristone and that patients sign a special form in order to receive their  
12 prescription, a challenge at a time of provider shortages throughout central and  
13 eastern Washington. Permanently removing the REMS in its entirety is critical to  
14 reducing the disproportionate harms of abortion restrictions.

15 **E. Threats to Abortion Providers**

16 24. Abortion remains highly stigmatized throughout much of the area  
17 PPGWNI serves. PPGWNI clinics—including our providers and patients—have  
18 been subject to violence and harassment.

19 25. In 1996, PPGWNI's Spokane Valley clinic was bombed by  
20 anti-abortion extremists. In 2015, an arsonist set fire to PPGWNI's clinic in  
21  
22

1 Pullman. In 2020, PPGWNI's Spokane clinic received a bomb threat. In 2021,  
2 PPGWNI's Spokane Valley clinic had its windows smashed.

3 26. PPGWNI providers and patients are also subject to routine  
4 harassment and intimidation from anti-abortion activists at our clinics. Recently,  
5 protestors associated with the "Church at Planned Parenthood" have gathered at  
6 PPGWNI clinics in an effort to disrupt clinic operations. These protesters have  
7 yelled at and verbally harassed patients, and have frequently interfered with clinic  
8 operations, including by blocking driveways and sidewalks. One group member  
9 in Yakima followed a PPGWNI provider to their home.

10 27. In 2021, a judge on the Spokane County Superior Court concluded  
11 that the group violated a Washington law prohibiting interference with health  
12 facilities and permanently enjoined the group from interfering with PPGWNI's  
13 clinic operations. Earlier this year the Court ordered the group to pay \$110,000  
14 in damages to PPGWNI, as well as attorneys' fees. Even so, the group has  
15 continued its protests and communicated to us that they intend to come back even  
16 harder.

17 28. This is part of a pattern since *Dobbs*, in which PPGWNI has seen  
18 protests intensify. According to our security data, protest activity post-*Dobbs* is  
19 50% higher than it was in 2021.

20 29. We have also seen these efforts to disrupt our operations spread to  
21 clinics where they did not previously occur. For example, we did not normally  
22

1 have protests at our Wenatchee clinic, but since *Dobbs*, we have seen regular  
2 protests there.

3 30. In addition to the harassment and violence, PPGWNI routinely faces  
4 cybersecurity threats from hackers trying to obtain information about patients and  
5 providers. Most commonly, we receive phishing emails that seek to obtain patient  
6 records and provider addresses. Because of the heightened risk of cybersecurity  
7 attacks, every PPGWNI staff member has to undergo annual IT security training.

8 31. Due to these various threats to PPGWNI's clinics, providers, and  
9 patients, we have had to devote considerable resources to security and patient  
10 privacy.

11 32. All PPGWNI clinics have security cameras and employ security  
12 guards to be on-site whenever the clinics are open. Clinics have locking  
13 vestibules known as "man traps" to ensure unauthorized people cannot enter the  
14 clinics. The clinics are also now equipped with bulletproof glass, following the  
15 incident in Spokane Valley in which the clinic's windows were smashed.

16 33. PPGWNI also maintains rigorous standards around patient privacy.  
17 We prohibit filming or recording equipment on site, maintain secure waiting  
18 areas and a rigorous check-in process, require providers to badge in and escort  
19 patients, etc. Nonetheless, we still face issues with protesters trying to film  
20 patients and providers, record license plates, and otherwise harass patients and  
21 providers.  
22

1 I declare under penalty of perjury under the laws of the State of  
2 Washington and the United States of America that the foregoing is true and  
3 correct.

4 DATED this 17th day of February 2023, at Spokane, Washington.

5 *Paul Dillon*

6 PAUL DILLON  
7 Vice President of Public Affairs  
8 Planned Parenthood of Greater  
9 Washington and Northern Idaho  
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# Exhibit 6

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10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF DONALD  
DOWNING R PH.

1 I, Donald Downing R. PH, declare as follows:

2 1. I am a Clinical Professor at the University of Washington School of  
3 Pharmacy. I am a licensed pharmacist in the State of Washington, License  
4 number, PH00009898. I make this declaration based on my personal knowledge,  
5 my training, and experience as a licensed pharmacist. All opinions expressed  
6 herein are to a reasonable degree of medical certainty more probably than not  
7 true.

8 2. I am familiar with the practice of pharmacy in the State of  
9 Washington because of my position as a licensed pharmacist in this state since  
10 1975 and for my education and training. I owned and operated two community  
11 pharmacies for thirteen years providing post-surgical care, home infusion  
12 services, and other clinical services. I also collaborated to start up several  
13 Washington State tribal health care clinics. I provided care at those clinics for  
14 years and I continue consult with tribes on health care issues.

15 3. I currently practice as a Clinical Professor at the University of  
16 Washington School of Pharmacy and serve as the co-director of its Community  
17 and Global Health Engagement Program. Since 1996, I have taught classes at the  
18 University of Washington School of Pharmacy to pharmacy students on many  
19 aspects of pharmacy, including pharmacy practice, law and ethics, reproductive  
20 health, and more. I have worked separately as a pharmacy consultant, assisting a  
21 number of pharmacies in many areas of pharmacy management. All of my work  
22

1 has enabled me to obtain an expertise in the regulatory and practical environment  
2 affecting pharmacists filling prescriptions in the State of Washington.

3 4. Pharmacy practice and management related to reproductive care is  
4 my specific specialty. I have provided over 400 sexual and reproductive health  
5 related talks and certificate trainings and have worked to enable pharmacists to  
6 be active participants in sexual and reproductive health care service. In 2014, the  
7 American Society for Emergency Contraception and the International  
8 Consortium for Emergency Contraception presented me with the Felicia Stewart  
9 Award for lifetime achievement in efforts to increase access to emergency  
10 contraception. In 2020, I was awarded the Bowl of Hygeia for these and other  
11 community service endeavors.

12 5. I currently am working on developing models of care for  
13 contraception and emergency contraception. I am also involved at the design  
14 stage of research to study strategies to reduce barriers to pharmacy participation  
15 in the prescription and dispensing of medication abortion. This latter study is in its  
16 initial stage of proposal and methods-development, though initial reception to the  
17 proposal indicates that it will receive broad-based funding support.

18 6. I am familiar with the amended Risk Evaluation and Mitigation  
19 Strategy (REMS) on dispensing mifepristone, which took effect on January 3,  
20 2023.

1           7. I am aware that under the January 2023 REMS only a certified  
2 pharmacy may dispense mifepristone.

3           8. To become a certified pharmacy, a pharmacy must agree to comply  
4 with a number of strict requirements for dispensing mifepristone. Pharmacies are,  
5 among other things, required to:

6           a. verify that the prescription it receives was written by a  
7 specially certified provider by confirming their completed  
8 Prescriber Agreement Form was received with the  
9 prescription or is on file with the pharmacy,

10          b. ensure delivery of the medication within four calendar days  
11 of receiving the prescription or comply with the additional  
12 requirement of confirming with the prescribing provider the  
13 appropriateness of prescribing the drug after four days,

14          c. designate an authorized representative to carry out the  
15 certification process, training of their staff, oversight, and  
16 implementation,

17          d. comply with various recordkeeping requirements, and

18          e. comply with audits.

19           9. As the co-Director of the University of Washington's School of  
20 Pharmacy Community and Global Health Engagement Program, I maintain  
21 routine contact with pharmacies in the State of Washington. I have spoken to a  
22

1 number of pharmacists in the State of Washington who would like to dispense  
2 mifepristone at their pharmacies but who are hesitant to do so because of the  
3 increased burden of becoming and operating as a certified pharmacy under the  
4 amended REMS. The REMS create additional administrative requirements  
5 beyond what is required for the vast majority of prescription drugs.

6 10. For a number of years, the community pharmacy industry  
7 nationwide has suffered from staff shortages primarily due to pharmacy benefit  
8 management organizations who have severely undermined the financial  
9 sustainability of large and small pharmacies alike. Staffing shortages and below-  
10 cost prescription compensation have caused many pharmacies to operate at an  
11 administrative deficit when they are filling prescriptions for an increasing number  
12 of drugs. As a result, each year the number of pharmacies operating in  
13 Washington State has been decreasing. The mifepristone REMS require  
14 pharmacies to take on extraordinary administrative tasks such as verifying that  
15 the provider is specially certified, providing additional training, and increased  
16 recordkeeping at a time when they are already under-staffed. The REMS will  
17 increase pharmacy workloads, as pharmacies will also be required to troubleshoot  
18 situations that arise in real time. For example, a patient could come to the  
19 pharmacy with a prescription but without having the required provider form. If  
20 the provider was not one that the pharmacy had not previously verified, then the  
21 pharmacy would need to take the additional step of verifying the provider and  
22

1 obtaining their mifepristone provider agreement form before the pharmacy could  
2 fill the prescription. Without adequate staff to take on this additional task, the  
3 pharmacy will need to delay dispensing this time sensitive medication. Because  
4 the timeframe for medication abortion is time-limited, and because the REMS  
5 require the pharmacy to fill the prescription within four calendar days, the  
6 administrative burden is an urgent one.

7 11. Small chain and family-owned pharmacies are the most heavily  
8 impacted by the January 2023 REMS. These pharmacies most often serve rural  
9 communities and lower populated areas. These smaller pharmacies are often ill  
10 equipped to meet the additional burden that the REMS create, because they are  
11 not large enough to absorb the extra staffing, training, administrative, and  
12 recordkeeping burdens of the REMS—all of which the pharmacy must undertake  
13 without compensation.

14 12. Less mifepristone availability at pharmacies because of the REMS  
15 will inevitably increase the likelihood that patients who live in rural and lower  
16 populated areas will need to travel long distances to find a certified pharmacy  
17 who carries mifepristone.

18 13. Compliance with the REMS will also pose increased exposure to  
19 potential legal liability for pharmacies and pharmacists. The REMS, in effect,  
20 require the pharmacies to police the enforcement of their terms by requiring the  
21 pharmacies to be the ones to ensure that the prescription that they have in front  
22

1 of them meets the various requirements of the REMS. The REMS do this by  
2 requiring pharmacies to verify the prescriber's certification in the mifepristone  
3 REMS program. In addition, with the increasing number of states across the  
4 United States that have banned distribution of mifepristone, pharmacy  
5 administrators must also factor into their operating costs the potential of having  
6 to face legal action initiated because of potential violation—or alleged  
7 violation—of out-of-state laws.

8 14. For most pharmacies in Washington, mifepristone will account for  
9 a very small part of their overall business, yet will account for a much larger part  
10 of their overall workload, giving these pharmacies very little return for their  
11 work. Because REMS require pharmacies to spend additional time with patients,  
12 additional time checking with prescribing providers, additional time with  
13 recordkeeping and compliance, as well as increase potential legal liabilities,  
14 pharmacies (and especially business leaders making decisions on behalf of  
15 pharmacies) are hesitant to invest in providing a service that is subject to such  
16 extensive, and unusual, regulation. The cost-benefit analysis will cause many  
17 pharmacies to conclude that dispensing this drug is not worth the increased  
18 burden, thereby decreasing availability of the drug in Washington State.

19 15. If the FDA had not placed these REMS on mifepristone, pharmacies  
20 in Washington State could dispense mifepristone in the same manner in which it  
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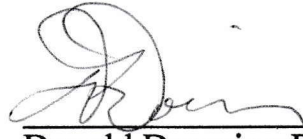
1 dispenses other drugs and many more pharmacies would likely choose to  
2 dispense mifepristone.

3 16. REMS are usually imposed on drugs that require more than the usual  
4 safeguards because of potential harm that the drug can cause. The imposition of  
5 the REMS on mifepristone does not fit this usual rule. There are numerous studies  
6 that confirm both the safety and the efficacy of mifepristone. Indeed, the  
7 restrictions placed on mifepristone by the FDA can actually increase risk to  
8 patients who would otherwise be able to quickly and safely terminate their  
9 pregnancies and are now faced with additional delay and lack of availability.

10 17. In my nearly fifty years as a pharmacist, pharmacy owner, professor,  
11 and reproductive-health specialist, I have routinely found that pharmacists in  
12 Washington State go to great lengths to provide high-quality reproductive  
13 medications to their patients. Nonetheless, the January 2023 mifepristone REMS  
14 present a series of burdens for pharmacies that are stigmatizing, administratively  
15 burdensome, confusing, expensive, and legally risky. The REMS will cause  
16 Washington pharmacies to opt out of dispensing mifepristone when they  
17 otherwise would dispense it if the drug did not carry a REMS. The decision not  
18 to become specially certified to dispense mifepristone will be made more often  
19 by smaller pharmacies, which are themselves more likely to serve rural, minority,  
20 or poor communities.

1 I declare under penalty of perjury under the laws of the State of Washington and  
2 the United States of America that the foregoing is true and correct.

3 DATED this 20th day of February, 2023, at Seattle, Washington.

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6 Donald Downing R. PH  
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# Exhibit 7

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NO. 1:23-cv-03026

DECLARATION OF DR.  
CHARISSA FOTINOS

1 I, Charissa Fotinos, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am the Medicaid Director of the Washington State Health Care  
5 Authority (HCA). HCA is the designated single state agency responsible for  
6 administering Washington's Medicaid program, known as Apple Health.

7 3. In this position I have primary responsibility for ensuring HCA  
8 offers high-quality, cost-effective care to Apple Health clients while adhering to  
9 federal Medicaid requirements.

10 4. The HCA operates Apple Health, Washington State's Medicaid  
11 program. Apple Health provides free or low-cost health care for income-qualified  
12 individuals. Pregnant individuals at or below 193 percent of the Federal Poverty  
13 Level are eligible for Apple Health.

14 5. The HCA also oversees the School Employee Benefits Board  
15 (SEBB) and the Public Employees Benefits Board (PEBB) which develop benefit  
16 plans, including health care coverage, for eligible public and school employees,  
17 retirees, and dependents.

18 6. Medication abortion is a common method for pregnant people in  
19 Washington to terminate a pregnancy within the first ten weeks of pregnancy. I  
20 am aware that, since 2000, the U.S. Food and Drug Administration has approved  
21  
22

1 a protocol for the medical termination of a pregnancy that involves taking  
2 mifepristone, followed by misoprostol.

3 7. Washington State funds medication abortions for Apple Health  
4 clients in need of that health care.

5 8. Based on available data, between state fiscal years 2015 and 2022,  
6 Washington State has seen an average 10% year-over-year increase in the number  
7 of patients seeking medication abortion care through Apple Health.

8 9. Based on available data, between state fiscal years 2017 and 2022,  
9 Washington State has seen an average 8% year-over-year increase in the number  
10 of patients seeking medication abortion care through the PEBB program.

11 10. Any limits on the availability of medication abortion in Washington  
12 State is highly likely to cause an increase in the number of surgical abortions for  
13 persons insured by Apple Health, SEBB, and PEBB. The corresponding increase  
14 in costs resulting from the more-expensive surgical procedure would be borne by  
15 Washington State. I anticipate these increased rates of surgical abortion due to  
16 the fact that misoprostol alone is not as effective in terminating a pregnancy as  
17 the two medications combined. With fewer completed abortions from  
18 misoprostol alone, there would be an expected increase in the number of surgical  
19 abortions.

20 11. Additional factors that could lead to an increase in costs for Apple  
21 Health, SEBB, and PEBB would be due to an increase in the number of visits for  
22

1 abortion related complications. The risk of excessive bleeding is higher after an  
2 abortion with misoprostol alone compared to the combination treatment. This  
3 could result in an increase in the number of office visits, emergency department  
4 visits and the need for additional interventions to treat excessive bleeding.

5 12. Additional costs could occur if misoprostol alone did not result in  
6 the termination of the pregnancy and the decision was made to continue the  
7 pregnancy. Misoprostol use early in pregnancy has been associated with an  
8 increased risk of facial and limb birth defects that increase the costs of care for  
9 the infant. Additionally, all these circumstances are likely to increase the amount  
10 of anxiety, stress and disruption experienced by the birth parents and any later  
11 caregivers. While specific costs are hard to quantify, an increase in visits and  
12 treatment for behavioral health conditions is likely.

13 13. I am aware that the same two-drug protocol described above for use  
14 in medication abortion is also used to treat people experiencing pregnancy loss  
15 (commonly referred to as miscarriage). Mifepristone, followed by misoprostol,  
16 has been shown to be safe and effective in the management of missed miscarriage  
17 in early pregnancy.

18 14. Any limits on the availability of mifepristone to treat missed  
19 miscarriage in Washington State is highly likely to cause an increase in the  
20 number of surgical interventions for persons insured by Apple Health, SEBB, and  
21 PEBB. The corresponding increase in costs resulting from the more-expensive  
22

1 surgical procedure would be borne by Washington State. I anticipate these  
2 increased rates of surgical intervention due to the fact that misoprostol alone is  
3 not as effective in treating miscarriage as the two medications combined. With  
4 fewer successful treatments from misoprostol alone, there would be an expected  
5 increase in the number of surgical procedures needed to treat pregnancy loss.

6 15. Additional factors that could lead to an increase in costs for Apple  
7 Health, SEBB, and PEBB would be due to an increase in the number of visits for  
8 missed miscarriage-related complications. As with the abortion context, use of  
9 misoprostol alone to treat miscarriage could result in an increase in the number  
10 of office visits, emergency department visits and the need for additional  
11 interventions to treat excessive bleeding.

12  
13 I declare under penalty of perjury under the laws of the State of  
14 Washington and the United States of America that the foregoing is true and  
15 correct.

16 DATED this 21st day of February, 2023, at Olympia, WA.

17   
18 \_\_\_\_\_  
19 Dr. Charissa Fotinos  
20 Medicaid Director  
21  
22



# Exhibit 8

1 ROBERT W. FERGUSON  
Attorney General  
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10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
EMILY M. GODFREY, M.D.,  
M.P.H.

1 I, Emily Godfrey, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am an Associate Professor with tenure in the Department of Family  
5 Medicine and in the Department of Obstetrics and Gynecology Division of  
6 Family Planning at the University of Washington (UW). I am board-certified in  
7 Family Medicine and have been practicing medicine since 2000. I completed a  
8 fellowship in Complex Family Planning and a Master of Public Health degree at  
9 the University of Rochester in 2003.

10 3. I am licensed to practice medicine in the state of Washington.  
11 Previously, I was licensed to practice in the states of Illinois and New York.

12 4. I obtained my undergraduate degree at the University of Wisconsin  
13 with a B.S. in English Literature. I received my medical degree from the Medical  
14 College of Wisconsin and completed my residency in family medicine at West  
15 Suburban Hospital in Oak Park, Illinois. My CV is attached as Exhibit A.

16 5. Throughout my 20+ year career in medicine, my research has been  
17 primarily focused on contraception and abortion care in primary care. I have  
18 received over \$4 million in federal funds, non-profit foundation and industry  
19 grants to support my research. I have published over 50 peer-reviewed articles in  
20 medical and public health journals. Additionally, I have published 32 other  
21 publications, including national and international guidelines, book chapters,  
22

1 editorials, curricula, videos and research tools, including a video featured by UW  
2 Medicine about medication abortion.<sup>1</sup>

3 6. I founded the University of Washington's Access, Delivered  
4 initiative, which consists of a provider toolkit that offers a step-by-step guideline  
5 for initiating telehealth medication abortion service within primary care  
6 practices.<sup>2</sup> The Access, Delivered provider toolkit has been downloaded by over  
7 2,000 providers and healthcare organizations interested in innovating their own  
8 services.

9 7. I currently run the UW Department of Family Medicine Women's  
10 Health Research and Scholarship Lab where we mentor undergraduate, medical,  
11 public and family medicine students and residents on topics related to  
12 contraception and abortion. I have received several awards for research  
13 mentoring over the course of my career.

#### 14 My Practice

15 8. I have been at UW since 2012, where I practice full-spectrum family  
16 medicine and conduct research related to women's health. I see patients at a UW  
17 \_\_\_\_\_

18 <sup>1</sup> UW Medicine, *Here's How Abortion Pills Work – and Why We Need*  
19 *Them* (Aug. 17, 2022) available at

20 <https://rightasrain.uwmedicine.org/well/health/medication-abortion>.

21 <sup>2</sup> UW Medicine, *Access, Delivered* available at  
22 <https://familymedicine.uw.edu/accessdelivered/>.

1 Medicine primary care clinic where I provide preventive care and treat acute and  
2 chronic health needs in infants, children, adolescents and adults. At this clinic, I  
3 also provide maternity care and women's health office-based procedures,  
4 including uterine ultrasound, contraceptive device insertions and removals, and  
5 first-trimester uterine aspiration. I teach and supervise general primary care,  
6 obstetrical care and reproductive health procedures to medical students, residents  
7 and fellows in family medicine. A routine and active part of my practice is  
8 treating patients seeking medication abortion. I prescribe mifepristone for  
9 abortion care approximately 2-3 times a month and am fully familiar with the  
10 FDA's risk evaluation and mitigation strategy (REMS) on dispensing  
11 mifepristone. I have safely prescribed mifepristone since it was first FDA  
12 approved in January 2000. During these two decades, I have counseled and  
13 prescribed mifepristone to at least one thousand patients in various clinical  
14 settings, including high-volume family planning and primary care clinics in New  
15 York, Illinois and Washington.

16 9. Over the course of my career, I have taught and supervised hundreds  
17 of residents, fellows and attending physicians on medication abortion assessment  
18 and prescribing in obstetrics/gynecology, internal medicine and family medicine.

19 10. When a patient comes to the clinic seeking medication abortion, we  
20 will generally begin the visit by reviewing the patient's medical history and  
21 symptoms. If they are eligible for medication abortion, I will discuss the risks  
22

1 and benefits and answer any questions they may have. As a doctor of Family  
2 Medicine, my duty is to ensure they receive and understand the information they  
3 need to then make an informed decision about their care.

4 11. If they decide to have a medication abortion, I explain both of the  
5 medications to them: mifepristone and misoprostol. I explain how the  
6 medications work and how they should take them. I also discuss the potential side  
7 effects and what they should expect to happen. I also explain what the patient  
8 should do if they start to experience any significant side effects, and then answer  
9 any questions the patient has. Finally, I will ask the patient if they consent to the  
10 abortion and if they do, at that time I will record their consent in their medical  
11 chart. Because it is required by the REMS, I will also have the patient review and  
12 sign the Patient Agreement Form in front of me. I will then dispense the  
13 medication by hand to the patient along with the Mifeprex Medication Guide. I  
14 generally encourage patients to follow up with me in one week and give them the  
15 clinic pager number where they can call and get immediate assistance with any  
16 urgent medication questions.

17 12. In order to remain compliant, I have patients review and sign the  
18 Patient Agreement Form as required by the FDA REMS. However, after  
19 counseling the patient myself and recording their verbal consent in the medical  
20 chart, I do not believe the Patient Agreement Form provides any benefit at all to  
21 the patient. If anything, this formal and redundant step harms the patient  
22

1 experience. An overemphasis on reviewing disclosure materials can make  
2 mifepristone sound like a scary and unsafe pill. But this is far from the truth. In  
3 fact, mifepristone is incredibly safe. It is probably one of the safest pills that  
4 people can be prescribed to take because it is highly targeted. Unlike  
5 chemotherapy or antibiotics, which can cause adverse effects while they are  
6 working to help patients, mifepristone works to inhibit just glucocorticoid and  
7 progesterone receptors and is in the blood system for less than 24-hours.  
8 Additionally, unlike other drugs I routinely prescribe to patients, such as  
9 oxycodone for chronic pain or amphetamine-dextroamphetamine for attention-  
10 deficit/hyperactivity disorder, mifepristone is not addictive and is taken only as a  
11 single dose. Aside from being incredibly safe, mifepristone is also very effective.

12 13. It is vitally important to note that mifepristone is a much needed  
13 medication not only for people who are seeking pregnancy termination, but also  
14 for people who are seeking to use medications for miscarriage management.  
15 Evidence demonstrates that treatment for miscarriage with mifepristone and  
16 misoprostol is better than treatment for miscarriage with misoprostol alone.<sup>3</sup> I  
17 prescribe mifepristone for miscarriage care to approximately one patient a month.

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18  
19 <sup>3</sup> Schreiber, C. A., Creinin, M. D., Atrio, J., Sonalkar, S., Ratcliffe, S. J.,  
20 & Barnhart, K. T., *Mifepristone pretreatment for the medical management of*  
21 *early pregnancy loss*, New England Journal of Medicine, 378(23), 2161-2170  
22 (2018).

1           14. The counseling I conduct around mifepristone for miscarriage  
 2 management is very similar to the counseling for medication abortion. Per the  
 3 mifepristone distributor, my patients experiencing a miscarriage also have to sign  
 4 the FDA's Patient Agreement Form in front of me. I have had miscarriage  
 5 patients who have been very reluctant to sign the Patient Agreement Form  
 6 because it is not targeted at their care and they do not want to sign a form meant  
 7 for abortion provision. Some find it confusing and others are upset by it. In those  
 8 instances, the Patient Agreement Form makes patient counseling much harder.  
 9 Removing the REMS program from mifepristone would allow me to provide  
 10 better care for my patients who need mifepristone for miscarriage management.

11 The REMS Discourage Family Medicine Doctors from Prescribing Mifepristone

12           15. Family medicine doctors have the highest number of office visits of  
 13 any medical specialty in the U.S., with more than 200 million annually and serve  
 14 as key access points for almost 70% of patients in the United States. All but 6%  
 15 of U.S. counties have family physicians, and historically, family medicine  
 16 doctors have provided a disproportionately greater share of obstetrical care in  
 17 rural areas compared to obstetricians or midwives.<sup>4</sup> They are often the only  
 18

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19  
 20           <sup>4</sup> Patterson, DG, Andrilla, CHA, Garberson, LA, *The Supply and Rural-*  
 21 *Urban Distribution of the Obstetrical Care Workforce in the U.S*, Policy Brief  
 22 #168, Seattle, WA, WWAMI Rural Health Research Center, University of



1 source of care, reproductive or otherwise, for adolescents and for patients in  
 2 underserved and rural areas.<sup>5</sup> During these visits, family physicians deliver a  
 3 broad range of acute, chronic, and preventive medical services for patients across  
 4 all ages and genders, including gynecological, obstetrical, and other reproductive  
 5 health services. Family medicine doctors value continuity of care throughout the  
 6 patient's life.

7 16. Because continuity of care is the crux of family medicine, all family  
 8 physicians are required to obtain prenatal and obstetrical skills during their  
 9 residency training. Carrying a pregnancy to childbirth is 30 times more dangerous  
 10 for the pregnant person than having an abortion, which is why first trimester  
 11 abortion care, especially with the use of medications, is within the scope of  
 12

13 \_\_\_\_\_  
 14 Washington (June 2020); Larson, EH, Andrilla, CHA, Garberson, LA, *Supply*  
 15 *and Distribution of the Primary Care Workforce in Rural America*, Policy Brief  
 16 #167, Seattle, WA, WWAMI Rural Health Research Center, University of  
 17 Washington (June 2020).

18 <sup>5</sup> *The Distribution of the U.S. Primary Care Workforce, Primary Care*  
 19 *Workforce Facts and Stats, No. 3*, Agency for Healthcare Research and Quality,  
 20 *available* *at*

21 <https://www.ahrq.gov/research/findings/factsheets/primary/pcwork3/index.html>

22 (last accessed Feb. 21, 2023).

1 practice for family medicine doctors.<sup>6</sup> The Accreditation Council for Graduate  
 2 Medical Education requires that family medicine residents have 100 hours or 125  
 3 patient encounters in gynecological care, which should include family planning,  
 4 miscarriage management, contraceptive services and options counseling for  
 5 unplanned pregnancy. The American Academy of Family Physicians (AAFP) has  
 6 more specific, competency-based guidelines, which include training to care for  
 7 people who are pregnant, to provide comprehensive contraceptive method  
 8 counseling and pregnancy options counseling, to evaluate gestational age and to  
 9 perform women's health office-based procedures such as endometrial biopsy,  
 10 subdermal and intrauterine contraceptive device insertions and removals.  
 11 Further, the Society of Teachers of Family Medicine group on Hospital and  
 12 Procedural Training issued a consensus statement that during residency, every  
 13 family medicine resident should be exposed and given the opportunity to train to  
 14

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15  
 16 <sup>6</sup> Raymond EG, Grimes DA, *The comparative safety of legal induced*  
 17 *abortion and childbirth in the United States*, Obstetrics and Gynecology 119:215-  
 18 9 (2012); Hoyert, D, Minino, A, *Maternal mortality in the United States:*  
 19 *Changes in coding, publication, and data release, 2018*. Hyattsville, MD:  
 20 National Center for Health Statistics (2020); Zane, S, Creanga, AA, Berg, CJ, et  
 21 al, *Abortion-Related Mortality in the United States: 1998-2010*, Obstetrics and  
 22 gynecology 126:258-65 (2015).

competence for independent provision of first-trimester aspiration abortion.<sup>7</sup> The National Academies of Sciences, Engineering, and Medicine issued evidence-based guidelines in 2018 for the safety and quality of abortion care in the United States, noting family medicine doctors routinely provide safe and effective medication and aspiration abortions.<sup>8</sup>

17. The mifepristone REMS is and continues to be a roadblock that keeps family medicine providers from integrating mifepristone into their regular practice.<sup>9</sup> When mifepristone was approved in 2000, one in three generalist doctors said they were planning to prescribe mifepristone in their practices.<sup>10</sup> Yet

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<sup>7</sup> Herbitter, C, Bennett, A, Schubert, FD, Bennett, IM, Gold, M, *Management of early pregnancy failure and induced abortion by family medicine educators*, J Am Board Fam Med 26:751-8 (2013).

<sup>8</sup> National Academies of Sciences, Engineering, and Medicine, *The Safety and Quality of Abortion Care in the United States* (2018), available at: <https://nap.nationalacademies.org/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states>.

<sup>9</sup> Raymond, EG, Blanchard, K, Blumenthal, PD, et al, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, N Engl J Med 376:790-4 (2017).

<sup>10</sup> Sheryl Gay Stolberg, *F.D.A. Adds Hurdles in Approval of Abortion Pill*, New York Times, Jun. 8, 2020, available at <https://archive.nytimes.com/www.nytimes.com/library/national/science/health/0>

1 research suggests that today, less than 5% of family medicine doctors actually  
 2 offer early abortion services in their primary care practices, primarily due to the  
 3 additional burdens and complications of ordering, storing and distributing  
 4 mifepristone under REMS.<sup>11</sup> The negative impact of this means that many  
 5 patients are not able to turn to their own, existing primary care physician or even  
 6 another physician in their community for medication abortion.

7 18. The January 2023 FDA REMS update has permanently removed the  
 8 “on-site” dispensing requirement of mifepristone, only to replace it with a  
 9 different, complicated process requiring pharmacy certification. In this scenario,  
 10 only special “registered” retail pharmacies can dispense mifepristone directly to  
 11 patients who, in turn, have to have a prescription prescribed from a “certified”  
 12 prescriber. It has been well documented that requiring a signed Prescriber

13 \_\_\_\_\_  
 14 [60800hth-abortion-drug.html](https://www.kff.org/womens-health-policy/will-1999-be-the-year-for-mifepristone/); National Survey of Women’s Health Care  
 15 Providers on Medical Abortion, *Will 1999 Be the Year for Mifepristone (RU-*  
 16 *486)? And, an Update on Women’s Other Options for Very Early Abortion*,  
 17 Kaiser Family Foundation, Aug. 31, 1998, available at  
 18 [https://www.kff.org/womens-health-policy/will-1999-be-the-year-for-](https://www.kff.org/womens-health-policy/will-1999-be-the-year-for-mifepristone/)  
 19 [mifepristone/](https://www.kff.org/womens-health-policy/will-1999-be-the-year-for-mifepristone/).

20 <sup>11</sup> Patel, P, Narayana, S, Summit, A, Gold, M, Morgan, ZJ, Peterson, LE,  
 21 et al, *Abortion provision among recently graduated family physicians*, Fam Med.  
 22 52:724-9 (2020).

1 Agreement discourages many family medicine doctors from prescribing  
 2 mifepristone.<sup>12</sup> There are multiple reasons for this. For one, certification requires  
 3 that prescribers be ready to “provide surgical intervention” or “have made plans  
 4 to provide such care through others” in the rare case that uterine aspiration is  
 5 needed. In my experience, this stipulation has impeded many family physicians  
 6 from prescribing mifepristone, since obtaining additional surgical aspiration  
 7 training is not feasible for many practicing family physicians. And even if  
 8 training were feasible, uterine aspiration procedures require that primary care  
 9 clinics purchase additional expensive equipment and instruments that can be  
 10 burdensome to store and maintain, especially if they are rarely used. Additionally,

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12 <sup>12</sup> Greenberg, M., Herbitter, C., Gawinski, B. A., Fletcher, J., & Gold, M,  
 13 *Barriers and enablers to becoming abortion providers*, Family medicine, 44(7),  
 14 493 (2012); Calloway, D., Stulberg, D. B., & Janiak, E., *Mifepristone restrictions*  
 15 *and primary care: Breaking the cycle of stigma through a learning collaborative*  
 16 *model in the United States*, Contraception, 104(1), 24-28 (2021); Godfrey, E. M.,  
 17 Fiastro, A. E., Jacob-Files, E. A., Coeytaux, F. M., Wells, E. S., Ruben, M. R., ...  
 18 & Bennett, I. M, *Factors associated with successful implementation of telehealth*  
 19 *abortion in 4 United States clinical practice settings*, Contraception, 104(1), 82-  
 20 91 (2021); Bennett, I., Aguirre, A. C., Burg, J., Finkel, M. L., Wolff, E., Bowman,  
 21 K., & Fleischman, J., *Initiating abortion training in residency programs: issues*  
 22 *and obstacles*, FAMILY MEDICINE-KANSAS CITY-, 38(5), 330 (2006).

1 community-based OB/GYNs are often unwilling to serve as a backup, especially  
2 if abortion is stigmatized in their communities. Another reason is that the  
3 existence of the REMS makes medication abortion appear different from other  
4 primary care services, and lends to misperceptions about the complexity and  
5 safety of medication abortion provision.<sup>13</sup> This also makes many providers  
6 reluctant to add it to their practice.

7 19. Another example of how REMS blocks access to care is that the  
8 Prescriber Agreement certification requires that providers are “able to assure  
9 patients access to medical facilities equipped to provide blood transfusions.”  
10 Such a stipulation is unnecessary, especially since the risk from massive  
11 hemorrhage for a first trimester medication abortion is incredibly rare, occurring  
12 at about 1 per 1000 prescriptions of mifepristone.<sup>14</sup> These data are aligned with  
13 my personal experience of prescribing mifepristone for more than 20 years in  
14 which only one of my patients to whom I prescribed mifepristone received a  
15 blood transfusion. Family medicine providers are often the only providers for  
16

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17 <sup>13</sup> Brown, B. L., Wood, S. F., & Sarpatwari, A., *Ensuring safe access to*  
18 *mifepristone during the pandemic and beyond*, *Annals of internal medicine*,  
19 174(1), 105-106 (2021).

20 <sup>14</sup> Creinin, MD, Grossman, DA, *Medication Abortion Up to 70 Days of*  
21 *Gestation*, ACOG Practice Bulletin Number 225, Obstetrics & Gynecology  
22 136(4):e31-e47 (Oct. 2020).

1 patients in vast rural areas where access to transfusion services may be hours  
2 away. Such stipulations serve as unnecessary barriers to care. When family  
3 medicine doctors cannot serve their patients living in rural or remote areas of the  
4 U.S., these patients are forced to travel to distant, or unfamiliar urban centers for  
5 their care, which causes them additional expenses, time away from home, and  
6 add the burden of finding coverage for work, childcare, elder care and other in-  
7 community responsibilities. Notably doctors are not required to sign such a  
8 certification before prescribing other medications that also carries a high risk for  
9 needing a blood transfusion, such as warfarin (used to prevent blood clots).

10 20. The REMS Prescriber Agreement also makes it so that a provider  
11 has to affirmatively “opt-in” in order to prescribe mifepristone. This, too, erects  
12 a big hurdle in the area of family medicine, as many individual family medicine  
13 providers work within larger health systems (like UW Medicine). Because of all  
14 of the stipulations on the Prescriber Agreement Form, and despite mifepristone’s  
15 incredibly safe record and family medicine’s training in obstetrical care, the  
16 decision to provide medication abortions can get bogged down within a larger  
17 healthcare system that cannot feasibly accommodate all of the extra steps  
18 required to meet REMS. Often those responsible for this decision are not  
19 healthcare providers themselves and erroneously see it as taking on too much  
20 legal or administrative liability. Without support from the larger institution, it is  
21 unlikely an individual provider will initiate medication abortion services in their  
22

1 clinical setting.<sup>15</sup> In fact, a research study I conducted on the implementation of  
2 medication abortion via telemedicine among 21 primary care providers suggests  
3 primary care providers working in larger clinics had more difficulty  
4 implementing medication abortion because of REMS. For example, having to  
5 safely and responsibly dispense mifepristone from the clinic when no other  
6 prescribed drugs are dispensed this way requires that the clinician take on the role  
7 of “pharmacist,” which is not what they are trained to do. Dispensing a drug in  
8 the middle of a clinical session also essentially disrupts the clinic flow of a large  
9 busy primary care practice, putting the provider behind schedule. Even with the  
10 mail-order pharmacy option to deliver mifepristone, large health systems can’t  
11 readily contract with these entities without layers of bureaucratic approval and  
12 changes in contractual policies. Because of these barriers, our study clinic  
13 champions were told that implementing medication abortion took away from  
14 other essential services offered by primary care.<sup>16</sup> This similar sentiment was

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15  
16 <sup>15</sup> Summit, AK, Lague, I, Dettmann, M, Gold, M, *Barriers to and enablers*  
17 *of abortion provision for family physicians trained in abortion during residency,*  
18 *Perspect Sex Reprod Health* 52:151-9 (2020).

19 <sup>16</sup> Godfrey, E. M., Fiastro, A. E., Jacob-Files, E. A., Coeytaux, F. M.,  
20 Wells, E. S., Ruben, M. R., & Bennett, I. M., *Factors associated with successful*  
21 *implementation of telehealth abortion in 4 United States clinical practice*  
22 *settings,* *Contraception*, 104(1), 82-91 (2021).



1 | noted in a different study with primary care providers practicing medicine in the  
2 | Midwest.<sup>17</sup>

3 | 21. Medication abortion via telehealth appointments can be safely  
4 | provided with similar efficacy and no increased risk of significant adverse events.  
5 | Evidence suggests that licensed family medicine providers can safely prescribe  
6 | medication abortion pills and serve an entire state through telemedicine.<sup>18</sup> Based  
7 | on my own research I conducted that will be published in the near future, my  
8 | findings show that telemedicine abortion care also reduces concerns about  
9 | patients having to walk through protestor activity and face congested waiting  
10 | rooms of abortion clinics. Telemedicine may also lower direct and indirect costs  
11 | of care for patients, including the costs associated with travel, lost wages and  
12 | childcare, as well as the cost of the service itself, all of which are known barriers  
13 | to timely abortion services.<sup>19</sup>

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14 |  
15 | <sup>17</sup> Calloway, D., Stulberg, D. B., & Janiak, E., *Mifepristone restrictions*  
16 | *and primary care: Breaking the cycle of stigma through a learning collaborative*  
17 | *model in the United States*, *Contraception*, 104(1), 24-28 (2021).

18 | <sup>18</sup> Godfrey, E. M., Thayer, E. K., Fiastro, A. E., Aiken, A. R., & Gomperts,  
19 | R., *Family medicine provision of online medication abortion in three US states*  
20 | *during COVID-19*, *Contraception*, 104(1), 54-60 (2021).

21 | <sup>19</sup> Margo, J, McCloskey, L, Gupte, G, Zurek, M, Bhakta, S, Feinberg, E,  
22 | *Women's Pathways to Abortion Care in South Carolina: A Qualitative Study of*

22. It is important that family medicine providers are empowered to offer medication abortion services via telemedicine to their patients in their own practices. The US COVID-19 Public Health Emergency (PHE) led to sustained changes in healthcare delivery, expanding telehealth for a variety of services, including in primary care.<sup>20</sup> Through my own research, family medicine providers have indicated that it is easy to include a medication abortion consultation via telemedicine, especially when the primary care office already has telemedicine in place for other types of consultations. As I stated above, my own research showed that REMS requirements, such as signing the Patient Agreement Form, and dispensing and shipping mifepristone to patients impede family medicine providers, especially those working in large health systems from readily implementing telehealth medication abortion.<sup>21</sup> As such, stand-alone,

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*Obstacles and Supports*, Perspectives on Sexual and Reproductive Health 48:199-207 (2016).

<sup>20</sup> Cortez, C et al., *Changes in Short-term, Long-term, and Preventive Care Delivery in US Office-Based and Telemedicine Visits During the COVID-19 Pandemic*, JAMA Health Forum, Jun. 9, 2021, available at <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2781917>.

<sup>21</sup> Fiastro, A. E., Sanan, S., Jacob-Files, E., Wells, E., Coeytaux, F., Ruben, M. R. & Godfrey, E. M., *Remote delivery in reproductive health care: operation*

1 online medication abortion entities such as Hey Jane, Choix, Aid Access,  
2 Abortion on Demand, etc. can more readily implement REMS. These online  
3 options are increasingly popular for patients seeking abortion services and serve  
4 as an important access point for patients, given the hostile political climate for  
5 abortion care access for millions of Americans.

6 23. Despite clear advantages of telemedicine abortion for some, it is not  
7 necessarily a good option for everyone. This is particularly true for individuals  
8 with limited access to technology, including limited broadband access;  
9 individuals with privacy or security concerns; and individuals with lack of  
10 experience with or knowledge of telemedicine. Plus, through a research study my  
11 team recently completed that evaluated sociodemographics between almost 1,700  
12 patients seeking in-clinic versus online medication abortion services, we found  
13 that younger individuals (less than 25 years), non-English speakers and those  
14 with at least one chronic medical issue were less likely to choose telemedicine  
15 and seek in-clinic services instead. These findings suggest the need to have both  
16 telemedicine and in-clinic medication abortion options to meet patient  
17 preferences. Further, since evidence suggests that close to 70% of female patients  
18 aged 18-44 years seen by family physicians have two or more chronic medical or  
19 mental health conditions, these study findings demonstrate the critically

20 \_\_\_\_\_  
21 *of direct-to-patient telehealth medication abortion services in diverse settings,*  
22 The Annals of Family Medicine 20(4), 336-342 (2022).

1 important role family medicine physicians have in providing comprehensive  
 2 family planning services, including early abortion care, to medically complex  
 3 patients of reproductive age.<sup>22</sup>

4 24. I also find that a certain number of patients want to meet with and  
 5 be treated by their own primary care physician—particularly on issues as  
 6 sensitive as pregnancy, abortion, and miscarriage.<sup>23</sup> This finding was also evident  
 7 in my own research study. Patients prefer to see their own primary care provider  
 8 because they experience undue concern and stress at having to be referred to  
 9 another provider or told to make a telehealth appointment with an unknown  
 10 provider. Given that many family medicine doctors value continuity of care and  
 11 generally handle all aspects of maternal care, carving out medication abortion for  
 12 differential treatment makes no sense and only stigmatizes the service further.

13 25. Plus, when abortion care is included in primary care, a family  
 14 medicine provider knows the patients' histories, can readily access the medical  
 15

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16  
 17 <sup>22</sup> Hsiao, CJ, Cherry, DK, Beatty, PC, Rechtsteiner, EA, *National*  
 18 *Ambulatory Medical Care Survey: 2007 summary*, National health statistics  
 19 reports 1-32 (2010).

20 <sup>23</sup> Rubin, S. E., Godfrey, E. M., Shapiro, M., & Gold, M, *Urban female*  
 21 *patients' perceptions of the family medicine clinic as a site for abortion care*,  
 22 *Contraception*, 80(2), 174-179 (2009).

1 record, and have already established trust with their patients. This often allows  
2 for a much better patient experience.

3 26. I am also concerned about the updated January 2023 REMS  
4 requirement that requires certified mifepristone prescribers to “submit the form to  
5 each certified pharmacy in which you intend to submit Mifeprex prescriptions.”  
6 Such a requirement is onerous, burdensome and completely unnecessary. In a  
7 busy primary care practice that serves hundreds of patients daily, it is impractical  
8 to expect every single primary care provider to submit a form to each certified  
9 pharmacy in the clinic’s catchment area. There may be potentially hundreds of  
10 pharmacies in which patients who seek care from primary care would want to  
11 pick up their prescriptions. To track which pharmacies are “certified” or not, and  
12 whether clinicians have “submitted” their form to each potential “certified”  
13 pharmacy is out of the scope of any mainstream clinic or provider.

14 27. Additionally, I am aware from conversations with colleagues and  
15 other providers that many have serious safety concerns about becoming a  
16 “certified prescriber” of a medication that some states have moved to criminalize  
17 and that is drawing so much media attention. This fear makes sense. As a family  
18 medicine doctor who is also an abortion-care provider, I have closely followed  
19 the increased violence against abortion care providers in recent years—and  
20 especially since the *Dobbs* decision. While I continue to identify as an abortion  
21 care provider and being a “certified prescriber” of mifepristone, many other  
22

1 family medicine doctors are not, and I can understand that concern. While  
2 certified pharmacies must attest to confidentiality measures, there is still a fear  
3 that an antiabortion employee at a local drug store or pharmacy may obtain that  
4 list and disclose the names of community-based providers who have signed a  
5 FDA Prescriber Agreement Form to protestors or those who threaten to harm  
6 abortion providers. This is a fear that the FDA has continued to ignore by  
7 continuing to require providers to become certified in order to prescribe  
8 mifepristone.

9 The REMS Makes It More Difficult for Patients to Access Mifepristone

10 28. Abortion care necessarily has a specific time window, and receiving  
11 care within that window creates urgency. Based on research I conducted with 30  
12 patients who recently sought medication abortion at a high-volume clinic in  
13 Washington State, I was saddened to hear just about every study participant  
14 describe how they first went to their regular OB/GYN or family medicine  
15 provider only to find out that they could only confirm that the patient was  
16 pregnant. Some of their providers referred the patient to the closest clinic that  
17 offers abortion services, only to be shocked to find out there was at least a 2-3  
18 week wait. Such news left many of these desperate participants to search online  
19 to quickly find another provider who could provide those services. No one plans  
20 an unplanned pregnancy. And thus, to make patients frantically search for a  
21 legitimate place for care at a moment when they face unexpected health  
22

1 challenges is both cruel and inhumane. Research shows that early medication  
 2 abortion options provide women and pregnant persons greater autonomy over  
 3 decision-making.<sup>24</sup> Allowing family medicine providers and primary care  
 4 providers to prescribe mifepristone the way they prescribe other types of drugs—  
 5 directly to the pharmacy of the patient’s choice without any registration or  
 6 certification—allows for dignified care.

7 29. Unfortunately, the personal choice to seek abortion care is still  
 8 stigmatized in many communities. Many people do not want to be seen going  
 9 into a clinic (like a Planned Parenthood) that is known to their neighbors and  
 10 others as a place that provides abortion services. Research I have been involved  
 11 with and the patients I have seen in my clinic suggests that patients prefer  
 12 obtaining abortion care in primary care rather than abortion clinics due to reasons  
 13 of trust, privacy, and continuity of care.<sup>25</sup>

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14  
 15  
 16 <sup>24</sup> LaRoche, K. J., & Foster, A. M, “*It gives you autonomy over your own*  
 17 *choices*”: *A qualitative study of Canadian abortion patients’ experiences with*  
 18 *mifepristone and misoprostol*, *Contraception*, 102(1), 61-65 (2020).

19 <sup>25</sup> Logsdon, MB, Handler, A, Godfrey, EM, *Women's preferences for the*  
 20 *location of abortion services: A pilot study in two Chicago clinics*, *Matern Child*  
 21 *Health J.* 16:212-6 (2012); Wu, JP, Godfrey, EM, Prine, L, Andersen, KL,  
 22 MacNaughton, H, Gold, M, *Women's satisfaction with abortion care in academic*

30. While the availability of medication abortion through telehealth appointments can help mitigate these stressors, the FDA's misguided decision to continue to require providers to become "certified providers" in order to prescribe mifepristone will continue to limit the number of providers available to staff such telehealth appointments and, in turn, limit the overall number of appointments available to patients. Moreover, as discussed above, telehealth appointments may not be appropriate for all patients for various reasons. For these patients, the REMS can have a devastating impact.

31. If a patient delays in finding a "certified provider," they may miss the very limited window in which to have a safe and effective medication abortion. This can cause more pregnant patients to delay care, and ultimately increase the need for second-trimester and surgical abortions, both of which have increased complication rates as compared to medication abortions.<sup>26</sup> These types of abortion are also more expensive and may put abortion out of the reach of some patients.

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*family medicine centers*, Fam Med.47:98-106 (2015); Summit, AK, Casey, LM, Bennett, AH, Karasz, A, Gold, M, *"I don't want to go anywhere else": Patient experiences of abortion in family medicine*, Fam Med. 48:30-4 (2016).

<sup>26</sup> Upadhyay, UD, Desai, S, Zlidar, V, et al, *Incidence of emergency department visits and complications after abortion*, Obstetrics and Gynecology125:175-83 (2015).



1           32. These harms will also be felt more intensely by patients in rural or  
2 medically underserved areas within Washington State, where there are already  
3 very few options for abortion care, and those patients may not have the financial  
4 means nor the family support needed to travel to a city that does have providers  
5 who can provide the care they need. First trimester medication abortion with  
6 mifepristone that can be taken at home or in the place of the patient's choosing  
7 has the potential to address abortion service disparities and health access  
8 inequities, particularly among disadvantaged populations. Tragically, the current  
9 guidelines still unduly require patients to sign redundant and unnecessarily  
10 frightening forms that impede access to care.

11 Implementation of the REMS at UW

12  
13           33. In addition to my patient clinic work and research work at UW, I  
14 have also been participating in a workgroup at UW charged with implementing  
15 the amended mifepristone REMS issued by the FDA on January 3, 2023.

16           34. I have been involved in numerous planning meetings on the  
17 implementation of the REMS, including managing how the REMS impacts  
18 workflows for providers and pharmacy staff.

19           35. I estimate that I spend 4 to 5% of my full-time equivalent working  
20 on issues related to implementation of the REMS, including updating clinic  
21 protocols, creating clinic work-flow documents, working with colleagues to  
22 figure out a system to ensures every provider in the UW Primary Care Clinics

1 who wants to prescribe mifepristone signs a Provider Agreement Form, and  
2 collating training materials to ensure other providers in the UW Primary Care  
3 Clinics are aware of how to assess and manage patient seeking medication  
4 abortion. I am also helping our Epic information technology team with changes  
5 to the Smartset, ensuring that patients who seek telehealth medication abortion  
6 can readily sign the Patient Agreement Form. I am helping to test and pilot these  
7 updates to make certain that our systems are in place for proper signatures from  
8 patients before prescriptions of mifepristone are sent to the pharmacy. I am  
9 helping to inform UW Medicine to create a website in which patients can get  
10 information about medication abortion, read the patient agreement form, and read  
11 the Mifeprex Medication Guide ahead of their appointments. My time spent on  
12 discussing, explaining, following and testing/piloting REMS implementation is  
13 time that I could have spent seeing more patients, training more residents, or  
14 working on important research.

15 I declare under penalty of perjury under the laws of the State of  
16 Washington and the United States of America that the foregoing is true and  
17 correct.

18 DATED this 22nd day of February, 2023, at Seattle, Washington.

19 

20 Emily Godfrey, M.D., M.P.H.

# Exhibit A

### **Curriculum Vitae**

Emily Maria Godfrey, MD, MPH  
University of Washington  
Department of Family Medicine  
Box 354982  
Seattle, WA 98105  
(206) 685-4895  
[godfrey@uw.edu](mailto:godfrey@uw.edu)  
Pronouns: she/her/hers

#### **1. Personal Data**

Place of birth: Chicago, Illinois  
Citizenship: USA

#### **2. Education**

1991 B.S., with Honors, English Literature, University of Wisconsin, Madison, WI  
1997 M.D., Medical College of Wisconsin, Milwaukee, WI  
2003 M.P.H, Research Design, University of Rochester School of Medicine and Dentistry, Rochester, NY

#### **3. Postgraduate Training**

1997-2000 Internship/Residency: Family Medicine, West Suburban Medical Center, Oak Park, IL  
2000-2002 Fellow, Family Planning, University of Rochester, Rochester, NY  
2003-2004 Fellow, Faculty Development, Stroger Hospital of Cook County, Department of Family Medicine, Chicago, IL  
2010-2012 Family Planning Epidemiology and Public Health Fellowship, Centers for Disease Control and Prevention, Atlanta GA  
2016-2017 Certificate Program in Patient Safety and Quality, University of Washington, Seattle, WA

#### **4. Faculty Positions Held**

2000-2003 Clinical Instructor in Family Medicine, University of Rochester, Rochester, NY  
2004-2005 Visiting Assistant Professor, Family Medicine, University of Illinois, Chicago, IL  
2005-2011 Assistant Professor (tenure track), Family Medicine, University of Illinois College of Medicine, Chicago, IL  
2005-2011 Affiliate Assistant Professor, Community Health Sciences, University of Illinois School of Public Health, Chicago, IL  
2010-2012 Assistant Research Professor, Obstetrics and Gynecology, University of North Carolina, Chapel Hill, NC  
2011-2012 Associate Professor (tenured), Family Medicine, University of Illinois College of Medicine, Chicago, IL  
2012- Associate Professor (tenured), Family Medicine, University of Washington School of Medicine, Seattle, WA  
2013-2017 Adjunct Associate Professor, Obstetrics and Gynecology, University of Washington School of Medicine, Seattle, WA

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2017- Associate Professor, Obstetrics and Gynecology, University of Washington School of Medicine, Seattle, WA

## 5. Hospital Positions Held

2000-2003 Family Medicine Physician, Highland Hospital, Rochester, NY  
 2001-2003 Emergency Medicine Physician, Highland Hospital Emergency Department, Rochester, NY  
 2002-2003 Attending Physician, Unity Health System Walk-in Care Clinic, Unity Hospital, Rochester, NY  
 2003-2012 Attending Physician, Departments of Family Medicine and Obstetrics and Gynecology, Stroger Hospital of Cook County, Chicago, IL  
 2004-2012 Attending Physician, Department of Family Medicine, University of Illinois Medical Center, Chicago, IL  
 2006-2012 Family Planning RHEDI Residency Director, Department of Family Medicine, University of Illinois, Chicago, IL  
 2013- Attending Physician, Departments of Family Medicine and Obstetrics and Gynecology, University of Washington Medical Center, Seattle WA

## 6. Honors and Awards

1995 Standing Ovation Award for diligent efforts on behalf of domestic violence education, Medical College of Wisconsin  
 1996 Standing Ovation Award for leadership shown through Physicians for Social Responsibility, Medical College of Wisconsin  
 2001-2002 Wyeth-Ayerst New Leaders Award  
 2002 Best Abstract Presentation, Association of Reproductive Health Professionals National Conference, La Jolla, CA (Title “Coping with abortion: Assessing women’s well being from patients’ and providers’ perspectives.”)  
 2004 Association of Reproductive Health Professionals Member of the Year Award  
 2005 Berlex Foundation Junior Faculty Development Workshop Award  
 2006 IL House of Representatives Sarah Feigenholtz Pro-Choice Leadership Award, Given to 11 physicians in IL who have made remarkable advances in providing reproductive health services to IL women  
 2006 **Grant Generating Project** Research Fellowship Award, University of Missouri Dept. of Family Medicine  
 2007 National Center of Excellence in Women’s Health AHRQ Workshop Travel Award  
 2008 Faculty Mentoring Award, University of Illinois College of Medicine  
 2009 Association of American Medical Colleges Early Career Women Faculty Professional Development Seminar  
 2011 The Linda K. Gunzburger Faculty Award for Excellence in Scholarship, University of Illinois Department of Family Medicine  
 2014 Best Conference Lecture, Contraceptive Technology National Conference  
 2015 Patient Safety Heroes Award, University of Washington Medical Center  
 2015 Midcareer Mentoring Award, Society of Family Planning  
 2017-2019 PCORI Ambassador Scholarship recipient Travel Award  
 2021 The UW Dept of Family Medicine Clinical Excellence Award -provided to the UWNC Northgate Repro Clinic (faculty/staff)

**7. Board Certification**

2000 Family Medicine, American Board of Family Medicine (ABFM)  
 2007, 2014 Recertification, ABFM

**8. Licensure to Practice**

1999-2012 Illinois (#036101057)  
 2000-2007 New York (#217837)  
 2012-pres Washington (#MD60303537)

**9. Diversity, Equity and Inclusion Activities**

2002-pres **Physician who includes comprehensive family planning services in primary care practice.** Unplanned pregnancies are most common among people with low incomes, or with jobs that do not provide health care coverage, which disproportionally affect women of color. Women and gender diverse individuals affected by racism and poverty have fewer options for high-quality contraception and other health care services. As a result, persons without adequate access to care are more likely to seek abortion services. My research and clinical focus on the inclusion of early abortion care in primary care helps to bring equity and justice in our community and our world.

2019-pres **Co-founder and lead mentor, UW Department of Family Medicine Women's Health Research and Scholarship Lab.** I mentor minority students and residents interested in pursuing a project related to women's health, either as the sole mentor or as a dyad team with a clinician-educator faculty member. To date, all undergraduate students were either African American or Asian American. Of the 10 medical students mentored, 9 were minority students (5 Asian-American, 1 African American and 2 Latinx). Our dyad faculty team mentored three Asian-American primary care residents.

2019-pres **Faculty member, search committee, Department of Family Medicine Reproductive Health Fellowship,** with emphasis on underrepresented minority recruitment.

2021-pres **Signed, Sealed, Delivered and Fleeing Oppression:** These two grant projects include a **community advisory board** aimed at including members from underrepresented minority communities.

**10. Professional Organizations**

1997-pres Member, American Academy of Family Physicians  
 2000-pres Member, National Abortion Federation  
 2000-2017 Member, Association of Reproductive Health Professionals  
 2003-2017 Member, Society of Teachers of Family Medicine  
 2004-pres Member, North American Primary Care Research Group  
 2004-2010 Member, IL Academy of Family Physicians  
 2004-pres Member, Physicians for Reproductive Health (formally Physicians for Reproductive Choice and Health)  
 2002-2006 Member, American Medical Women's Association  
 2006-pres Fellow, Society of Family Planning  
 2013-pres Fellow, American Academy of Family Physicians  
 2016-2020 Founder/Board Chair, Cystic Fibrosis Reproductive and Sexual Health Collaborative (cfreshc.org)

**11. Teaching Responsibilities***Undergraduate student courses:*

- 2014-2020 Course Director, Independent Study in Clinical Research Trials for undergraduate students. Developed curriculum with associated readings and videos. Work with 1-2 students independently per quarter.
- 2014-2018 Advisor, Alpha Epsilon Delta (AED) (Pre-med honor society). Undergraduate students contact me to shadow me in clinic and hospital rounds.

*Medical student/PA student courses:*

- 2007-2010 Director, "Independent Study Research Course" in Family Medicine. University of Illinois College of Medicine. Created independent research course in which learners think critically about a research question related to women's health, develop data collection design and write a final project paper.
- 2007-2009 Seminar developer, "I think I might be pregnant: A primer on contraception, abortion and options counseling for medical students." University of Illinois College of Medicine. Created and provided 2<sup>nd</sup> year medical student lecture, small-group case-based tutorial and selected required readings (~150 students annually).

*Resident courses:*

- 2006-2011 Co-Director (~50% responsible), "Values Clarification: An Interactive Workshop." UIC Department of Family Medicine. Co-developed with Behavioral Scientists. Co-lead a 2.5-hour annual resident workshop presented to first-year Family Medicine residents during their mid-year orientation week.
- 2006-2011 Co-Director (~50% responsible), "Options Counseling Skills. UIC Department of Family Medicine. Co-developed and led a 1.5-hour biannual case-based resident workshop presented to all Family Medicine residents during their required didactic teaching time.
- 2013 Instructor, "Systematic Reviews: The Foundation of Evidence-based Practice." UW Department of Family Medicine Workshop. Developed and co-presented two 3-hour workshops for all faculty and residents, collaborated with UW Health Sciences librarians.

*Graduate Student courses:*

- 2004-2010 Course Director, "Family Planning – Policies and Practices" (CHSC 594), UIC School of Public Health. Developed and led a 3-credit graduate-level course focusing on the interventions and the impact of family planning from the public health perspective. Organized syllabus and readings, arranged for guest lectures, presented lectures, facilitated fieldwork experiences and led discussions.
- 2018, 2019 MEDEX annual GYN exam proctor.

*Faculty level courses:*

- 2007- Implanon Training: Instruction on placement and removal of implantable contraception (Conducted sessions for faculty and residents in 2007-2010, 2013-2021)
- 2013 Instructor, "Systematic Reviews: The Foundation of Evidence-based Practice." UW Department of Family Medicine Workshop. Developed and co-presented two 3-hour workshops for all faculty and residents, collaborated with UW Health Sciences librarians.

*International teaching:*

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- 2012 Visual inspection of the cervix with acetic acid (VIA). Training of local nurses and midwives in rural Senegal. In conjunction with Peace Care, Chicago, IL and Peace Corps volunteers based in Senegal (Feb 2012).

*Research Trainees:*

Undergraduate Students:

- AY15 Mentor, Niveda Shikar (UW Senior). Completed literature review of video use for counseling in the healthcare setting. Also learned about IRB applications, recruitment strategies, data collection; helped complete source documents for ACCCUSS study. Presented at the UW Undergraduate Research Symposium, 2015.
- AY15-18 Mentor, Tatiana Josephy BS, (UW post-bachelor/pre-med student). Helped to develop a contraceptive registry for women with complex medical conditions. Submitted PCORI P2P successfully funded June 2016.
- AY15 Mentor, Hae (Angel) Lee (UW Freshman/Sophomore, Quarters). Learned about systematic review and meta-analysis methodology. Assisted with literature search related to contraceptive exposure and birth defects. Presented at the UW Undergraduate Research Symposium, 2015. Currently an engineer in California.
- AY15-16 Mentor, Savannah Burr (UW Junior/Senior, Neuroscience). Completed term paper and research project related to how teens and young adults can maintain confidentiality when on parent or guardian insurance plans. Presented at UW Undergraduate Research Symposium, 2016. Admitted to UW Physical Therapy School in 2017. Currently a physical therapist at Seattle Children's Hospital.
- AY20-21 Mentor, Sajal Sanan (UW Senior, Microbiology). Analyzed data for the project entitled, *Comparison of completeness and timeliness of Paper, Text and Smartphone App Bleeding Diaries*. Presented at the 2019 NAPCRG National Conference (Toronto, Canada). **Awarded travel funds by the UW Mary Gates Foundation (2019), stipend from the Cambridge Reproductive Health Consultants for participation on the Access, Delivered project manuscript (2021), and WA State Society Daughters of the American Revolution Evans' Medical School Scholarship (2021).** Currently UW School of Medicine student Class of 2025.

Master of Public Health Students:

- AY14 MPH Committee Member, Leah Torres MD, Family Planning Fellow and MPH candidate, RCT of focused contraceptive counseling and case management versus usual care in women postpartum from a preterm birth. Currently an OB/GYN practicing in Alabama.
- AY14 Co-mentor, Arahadana Thapararana, UW MPH student, survey study evaluating factors associated with acceptance of contraception after abortion in Nepal. 2014.
- AY15-16 Supervisor, Alison Ojanen-Goldsmith, MSW, UW MPH student. Completed a practicum on evaluating family planning services in primary care and types of clinicians who have completed CME related to CDC family planning guidance. Currently the Director of Research for Planned Parenthood MN.
- AY19-20 Supervisor, Erin Thayer. MPH student. Research Coordinator for the PCORI Eugene Washington Award to build patient-centered outcomes research (PCOR) in the cystic fibrosis community and determining best platforms for online PCOR collaborations. Presented at the 2019 NAPCRG National Conference (Toronto, Canada). Awarded travel funds by UW Graduate and Professional Student Senate (2019), stipend from the Cambridge Reproductive Health Consultants for participation on the Access, Delivered project manuscript (2021). Currently a data analyst for the Department of Family Medicine at University of Southern California, and continues to be a consultant for UW Access Delivered project.



AY22 MPH Committee Member, Linda Guijosa, MPH Candidate, Executive Master of Public Health Degree Program UW School of Public Health.

AY22 Mentor/Supervisor, Brittany Rattiliff MPH Candidate (2020-2022), Executive Master of Public Health Degree Program UW School of Public Health. Project: Engagement of members from underrepresented communities regarding abortion care and access. **Awarded project funds by UW Department of Family Medicine JEDI Committee.** Abstract accepted to the 2022 Association of Clinicians for the Underserved (ACU).

#### Medical Students:

AY10-12 Research mentor, Anita Bordioli, MD candidate, Retrospective review of medical abortion in the student health care clinic setting. (2009-2012). Study published in Journal of American College Health, 2012.

AY15 Medical Student Research Training Program (MSRTP) Mentor, Michael Nguyen, MD candidate, Systematic review on strategies to disseminate family planning guidelines into primary care, Summer 2014.

AY17 Grant application mentor, Ryann Milne-Price, MD/MPH Candidate, Reproductive Health Education in Family Medicine (RHEDI) successful grant application for Western Montana Family Medicine Residency Program.

AY20 Co-faculty mentor (2019, 2020), Suzette Guzman, University of Chicago medical student. Investigating faith-based family medicine residency programs and family planning training. Abstract accepted as student poster at the 2020 NAPCRG conference. **Awarded the Student Scholarship Award for 2021 STFM Medical Education Conference (virtual).**

AY21 Faculty mentor, Anh Nguyen (UW I<sup>3</sup> Program). Investigating family planning training in family medicine and internal medicine residency programs. **Project abstract accepted as oral presentation at the 2021 Western Medical Research Conference, and as a poster at the 2021 Society of General Internal Medicine.**

AY21 Faculty mentor, Madison Miller (UW I<sup>3</sup> Program). Investigating controversial public health topics in mainstream media and use of university affiliation. **Project abstract accepted as poster to the 2021 Society of Teachers of Family Medicine Conference (Virtual). Received a 2021 UW Medical Student Conference Travel Award.**

AY21 Faculty mentor, Ramya Kommidi (New York Institute of Technology College of Osteopathic Medicine) Mentored student on Access, Delivered project during the 3-week AMSA "Reproductive Health Mentorship Sprint."

AY21 Mentor, L'Oreal Kennedy (UW 2<sup>nd</sup> year medical student). Seattle Children's: Antiracism starts at the top. **Successfully submitted [Letter to the Editor](#), Seattle Times, January 8, 2021.**

AY21 Faculty mentor, Isabella (Bella) V. Stokes (UW 2<sup>nd</sup> year medical student). Assisted with the Access Delivered project. **AAFP Family Medicine Leads Emerging Leader Institute Awardee, 2021 Scholar.** FM Leads Institute (WWAMI Abortion Project) was the **Winner of the 2022 UW DFM Department Fair & Scholarship Forum Best Visual Presentation.**

AY21 Mentor, Tatiana Josephy (University of Chicago, 4<sup>th</sup> year medical student). First author of two published papers in 2021 related to (1) utilizing a smart-phone app for research participants to report bleeding and other associated symptoms during contraception use and (2) describing the establishment of a contraceptive registry that combines clinical outcomes with contraceptive survey data.

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AY22 Faculty mentor, Nikeeta Shah (Western University of the Health Sciences, 4<sup>th</sup> year medical student). Communication needs of patients accessing online medication abortion services. **Abstract accepted as student oral presentation at the 2021 NAPCRG conference (virtual).**

Residents:

AY15-16 Mentor, Alyce Sutko MD, MPH, UW Department of Family Medicine PGY-3, “Contraceptive Adherence among women with hypertension in primary care.” STFM submission.

AY18 Mentor, Elise Gelston MD, MPH, UW Department of Family Medicine PGY-2. “Preserved female sexual function and quality of life after Copper IUD placement.” UW DFM Scholarship Forum (2019) – **voted honorable mention.**

AY19-20 Mentor, Viet Nguyen MD, UW Department of Family Medicine PGY-3. Phleboliths mistaken for intraperitoneal TCu380A IUD in the presence of missing strings: A case report. **Successfully published in BMJ Case Reports, March 2021.**

AY20 Mentor, Nina Tan MD, UW Department of Internal Medicine, PGY-2. Advancing Access to Medication Abortion in Primary Care: Conducting a Needs Assessment for Family Planning Training Among Internal Medicine Primary Care Residency Programs. **Successfully funded grant application to the Society of Family Planning Emerging Scholars Award, [July 2020](#).**

AY21 Mentor, Monica Agarwal MD, UW Department of Family Medicine PGY-3. The Trump Administration is systematically undermining women’s reproductive rights. **Successfully published as an [Op-Ed on Kevin, MD](#), September 14, 2020.**

Fellows:

AY13 Mentor, Lisa Callegari MD, UW Post-doctoral fellow in HSRD at Puget Sound VA. I was a supervisor for Lisa’s MPH practicum on doing a systematic review on reproductive life planning tools.

AY15 Co-mentor, Lyndsey Benson MD, MS, UW Family Planning Fellow in Obstetrics and Gynecology. Provided advice and reviewing her project on heterosexual anal intercourse. FFP-funded project.

AY16 Co-mentor, Ying Zhang MD, UW NRSA Fellow in Family Medicine. Mentored practicum project evaluating reproductive health services among Somali refugee populations in Seattle, AAFP Foundation funded project.

AY17 Co-mentor, Traci Kazmerski, MD Boston Children’s Hospital Pediatric Health Services Research Fellow in the Division of Pulmonary and Respiratory Diseases. Mentored on sexual and reproductive health Career Research Award to the Cystic Fibrosis Foundation. Mentored on CF Reproductive and Sexual Health Collaborative submission to the North American CF Conference, November 2017. **Fellow abstract was selected as semi-finalist for the Junior Investigators Best Abstract in Clinical Research.**

AY18 Co-mentor, Rebecca Taub MD, UW Family Planning Fellow in Obstetrics and Gynecology. Mentoring on QI skills as a participant of the project funded through the UW Patient Safety Innovations Program.

Faculty:

AY14-15 Co-mentor, Lois Thetford PA, UW Department of Family Medicine, MEDEX faculty, “How important is contraception in the health seeking behavior of homeless youth?” Study for publication.

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- AY15 Mentor, Brandi Shah MD, MPH, Attending physician, PAC Med, Enhancing teenage sexual-reproductive health care in primary care settings. Submitted for RWJ award, not funded. Currently a student health provider at the University of Alabama.
- AY20-pres Mentor, Alexa Lindley MD, MPH. UW Department of Family Medicine, Residency Section faculty. We initiated the **DFM Women's Health Research and Scholarship Lab**, a dyad mentorship model intended to support and empower FM residents and UW medical students. The goal of this program is to help residents, Residency Section and Research Section faculty meet their scholarship milestones, while focusing on coaching and guiding the learner to pick a project related to women's health that they are passionate about and develop scholarship skills that are important to them. This program was presented at the UWDFM Residency Scholarship and Research teaching session. A manuscript describing this program has been accepted for publication in Medical Education.
- AY21-pres Mentor, Kim Kardonsky, MD UW Department of Family Medicine. Enhancing family planning services in primary care: A systematic Review. Currently working on manuscript for publication.

## 12. Editorial Responsibilities

- 2017-2018 Editor, Primary Care--Clinics in Office Practice: Women's Health

## 13. Special International and National Responsibilities

- 2006-2007 Consultant, Midwest Professional Research and Educational Services, Milwaukee WI. Developed IUD training program for mid-level providers.
- 2005-2012 Governance Board Member, Association of Reproductive Health Professionals
- 2008 Consultant, **World Health Organization (WHO) Special Programme of Research, Development, and Research Training in Human Reproduction**, Geneva Switzerland.
- 2006-pres Speaker, Merck Pharmaceuticals. Provide educational session on HPV vaccine and etonorgestrel birth control implant
- 2006-pres Curriculum Advisory Committee member, TEACH Early Abortion Training Curriculum, UCSF Bixby Center for Global Reproductive Health: San Francisco, CA.
- 2009 Discussant, Non-contraceptive use of the levonorgestrel intrauterine system in a managed care setting. 46<sup>th</sup> Annual Conference of the Association of Reproductive Health Professionals and Society of Family Planning, October, Los Angeles, CA.
- 2009-2012 Abstract Reviewer, Association of Reproductive Health Professionals Annual Meeting.
- 2010-2015 Abstract Reviewer, **Society of Family Planning Scientific Review Committee**.
- 2011 Clinical Advisor, Quick Reference Guide for clinicians: Choosing a Birth Control Method, Association of Reproductive Health Professionals.
- 2011-2012 Co-chair, Scientific Committee, Association of Reproductive Health Professionals Annual Meeting.
- 2011 Member, Male Clinical Services for Title X Family Planning Guideline Revision, Health and Human Services, Office of Population Affairs Expert Panel.
- 2011 Member, Community Outreach for Title X Family Planning Guideline Revision, Health and Human Services, Office of Population Affairs Expert Panel.
- 2012-2015 Member, **Centers for Disease Control and Prevention (CDC)**, Women's Clinical Services for Title X Family Planning Guideline Revision, Health and Human Services, Office of Population Affairs Expert Panel.
- 2012 Member, National Meeting Planning Committee, Association of Reproductive Health Professionals Annual Meeting.
- 2012-2020 *Ad hoc* reviewer, National Fellowship in Family Planning Fellow Grant Program

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- 2013-2017 Guideline Committee Member, **World Health Organization (WHO)** Guideline on sexuality counseling for health care providers
- 2014-2017 Member, **Society of Family Planning** Education Committee
- 2014-pres Member, **Centers for Disease Control and Prevention (CDC)** *US Medical Eligibility Criteria for Contraceptive Use* (US MEC) and *US Selected Practice Recommendations for Contraceptive Use* (US SPR) Expert Working Group.
- 2014-pres Member, Upstream USA National Medical Advisory Committee.
- 2015, 2017 *Ad hoc* reviewer, **Society of Family Planning Research Fund**.
- 2012-2018 Site Visit Evaluator, Complex Family Planning Fellowship in Family Medicine (Albert Einstein/Montefiore Department of Family and Social Medicine and UCSF Department of Family and Community Medicine)
- 2016 Z-CAN Proctor, **Centers for Disease Control and Prevention (CDC)** Public Health Emergency Response to Zika, September 2016, Puerto Rico
- 2016 Moderator, Vulnerable Populations oral sessions, 2016 NAPCRG Annual Meeting.
- 2017-2022 Member, **North American Primary Care Research Group (NAPCRG)** Program Committee
- 2017-pres Council member, **North American Primary Care Research Group (NAPCRG) PaCE (Patient and Clinician Engagement) Program**. My work in this group is featured in the [PaCE Video](#).
- 2017-pres Abstract reviewer, **Patient-Centered Outcomes Research Institute (PCORI)** Ambassador Program
- 2016-2020 **Founding Chair**, Cystic Fibrosis Reproductive and Sexual Health Collaborative (CFReSHC)
- 2018 Moderator, Abortion Provision: Maintaining scope of practice for primary care providers alongside family planning specialists. North American Forum on Family Planning 2018 Annual Conference.
- 2021-pres Member, **Robert Graham Center** Patient and Clinician Engagement (PaCE) Advisory Committee
- 2023-pres **Vice Chair**, NAPCRG Program Committee

#### 14. Special Local Responsibilities

- 2013, 2016 Nominee Reviewer, Liu Bie Ju Award for Excellence in Women's Health, University of Washington Medical Student Poster Sessions.
- 2013-pres *Ad hoc* reviewer, Pilot grant applications, UW Institute of Translational Health Science Center.
- 2013-pres Faculty, UWNC Northgate Repro Health Clinic, UW Dept of Family Medicine
- 2014-2015 **Chair**, UW Department of Family Medicine Annual Fair Planning Committee
- 2014 Member, UW Department of Family Medicine Industry Committee
- 2015 Member, UW Department of Family Medicine Research Section Incentives Committee
- 2015-2016 Co-Director, National Research Service Award (NRSA) in the UW Department of Family Medicine
- 2017-2019 **Standing Member**, UW Royalty Research Fund Review Committee
- 2019 Assistant Director, Reproductive Health & Advocacy Fellowship Program, UW Dept of Family Medicine
- 2017-pres MEDEX Proctor – supervise and teach primary care physical exam and summative clinical reasoning skills to MEDEX students
- 2019-2021 Member, Medical Student Research Training Program Committee, UW School of Medicine
- 2020-pres Faculty, Reproductive Health & Advocacy Fellowship Program, UW Dept of Family Medicine

**15. Clinical Activities:** I currently spend 15% FTE providing clinical services: 10% FTE is dedicated to my own primary care practice and 5% as a faculty member for the UW Northgate Reproductive Health Clinic, a service that was awarded the 2021 UW Department of Family Medicine Clinical Excellence Award.

Between 2013 and 2018, I took call several times a month and served as the Family Medicine Service (which included Labor and Delivery) hospital attending 3-4 weeks annually, had my own primary care practice one day a week and saw patients weekly in the Reproductive Health Clinic. I also saw patients and precepted residents at the King County/NeighborCare OB clinic in Columbia City. Until 2020, through my joint appointment in the UW Department of OB/GYN, I provided weekly clinical care and supervising OB/GYN, internal medicine and family medicine residents and medical students in the Family Planning Clinic at the Roosevelt Women's Health Care Clinic.

## 16. Research Funding

### *Current*

- 2023-2024 Evaluate potential delays in access to abortion services in Washington state following the U.S. Supreme Court decision (Balkus/Godfrey – Co-PI)  
UW Population Health Initiative Tier 2 pilot grant (Autumn 2022)  
A multi-disciplinary team with a WA state community partner will develop a system to efficiently extract and summarize electronic medical records data to evaluate potential delays in abortion access in WA state  
Annual Direct Costs: \$95,000
- 2022-2023 Fleeing oppression: Seeking abortion services in permissive states (Godfrey – PI)  
Society of Family Planning Research Fund (SFPRF16-IAA4)  
Uses an integrated theoretical framework to study patient-centered access to abortion service health care in WA state  
Annual Direct Costs: \$50,000
- 2022-2023 Pragmatic Evaluation of Adaptive Treatment Regimens in the Post-CFTR Modulator Era: the RELIEVE Project (Szczesniak/Gifford -PI)  
Cystic Fibrosis Foundation  
This study seeks to understand the decision-making process of discontinuing treatment therapies among individuals with cystic fibrosis in the era of highly effective modulator therapy  
Annual Direct Costs: \$51,192  
Role: Patient/Stakeholder engagement content expert
- 2020-2023 Access, Delivered (Godfrey – PI)  
UW Medicine Family Planning Fund – Anonymous donation  
Studies the implementation of novel telemedicine and mifepristone by mail abortion services in primary care and independent reproductive health clinics.  
Total funding: \$510,000
- 2020-2023 MENstrual Symptom Tracking to Understand and Assess (women) Living with CF (MENSTRUAL) (Godfrey/Sufian – Co-PI)  
Cystic Fibrosis Foundation (CFF) (GODFRE20A0)  
This is a nation-wide longitudinal cohort study that uses a daily menstrual tracking app to assess whether CF-related symptoms are menstrually related.  
Annual Direct Costs: \$80,000
- 2019-2023 Assessment of contraceptive safety and effectiveness in Cystic Fibrosis (Godfrey/Aitken – Co-PI)  
Cystic Fibrosis Foundation (CFF) (GODFRE19A0)



This is a multi-site retrospective cohort study that examines the safety and effectiveness of contraception among women with cystic fibrosis by linking self-respondent contraceptive data with clinical data from the CFF Patient Registry.  
Annual Direct Costs: \$350,000

### ***Completed***

- 2021-2022 Access to and acceptability of telemedicine medication abortion in primary care (Srinivasulu/Godfrey – Co-PI)  
Society of Family Planning Research Fund (SFPRF15-MSD4)  
Studies patients' experiences and accessibility of receiving telemedicine medication abortion services and pill delivery innovated by a large, urban primary care health system during the COVID-19 pandemic.  
Annual Direct Costs: \$80,000
- 2021-2022 Signed, Sealed, Delivered: Patient experiences of telehealth medication abortion services at the Cedar River Clinics (Godfrey – PI)  
Society of Family Planning Research Fund (SFPRF15-MSD2)  
Compares how medication abortion services offered by telemedicine shifts the accessibility of abortion care to patients.  
Annual Direct Costs: \$80,000
- 2018-2021 Building Online Research Partnerships to Improve Sexual and Reproductive Health for Women with Cystic Fibrosis (Godfrey – PI)  
Patient-Centered Outcomes Research Institute (PCORI) (UWASH-10569)  
The overall goal of this engagement award is to build capacity for patient-centered outcomes research within the Cystic Fibrosis patient, research and clinical community.  
Total funding: \$393,000
- 2015-2019 Anticipatory Counseling on LNG IUS Continuation, Utilization, and Satisfaction: A Pilot Study (Godfrey-PI)  
Bayer Pharmaceuticals Investigator-Initiated Grant (# WH-2014-018)  
This goal of this study is to test an anticipatory counseling intervention among new LNG using video technology.  
Total funding: \$293,118
- 2016-2018 Building a National Contraceptive Registry for Multiple Complex Medical Conditions: Improving contraceptive care for women through engagement (Godfrey – PI)  
Society of Family Planning Research Fund (SFPRF10-II2)  
The goal of this planning grant is to build a proof-of-concept contraceptive registry for women with cystic fibrosis, and with plans to add additional medical conditions.  
Annual Direct Costs: \$50,000
- 2016-2018 Advancing reproductive health wellness between patients with Cystic Fibrosis, healthcare providers and researchers (Godfrey – PI)  
Patient-Centered Outcomes Research Institute (PCORI) (5140022)  
Funding to form a patient-driven task force to address reproductive health-related concerns and to develop comparative effectiveness research questions related to reproductive life span care for patients with cystic fibrosis.  
Annual Direct Costs: \$40,000
- 2017-2018 Improving efficiency and effective contraceptive counseling in UW primary care and women's health clinics (Godfrey – PI)  
UWM Patient Safety Innovation Program  
The goal of this project is the increase patient satisfaction and reduce clinician counseling time in the UW-affiliated primary care and women's health clinics using a novel anticipatory video for the hormonal IUD.  
Total funding: \$50,000

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- 2015-2017 Translating evidence-based family planning research into primary care clinical settings (Godfrey – PI)  
Society of Family Planning Research Fund Mid-Career Award (SFPRF9-MC1)  
This goal of this study is to study how family planning guidelines are best implemented into primary care.  
Total funding: \$80,000
- 2015-2018 A multi-center, double-blinded, randomized, phase IV 6-month pilot study to compare bleeding patterns, satisfaction and quality of life among new Copper 380A IUD users treated with naproxen sodium (440 mg twice daily) versus placebo (Godfrey - PI)  
Teva Pharmaceuticals Investigator-Initiated Grant (DR304-WH-60191)  
This goal of this study is to test the effectiveness of naproxen as treatment for heavy or prolonged menstrual bleeding with copper IUD use.  
Total funding: \$174,058
- 2015-2016 A Study Measuring Core Body Temperature Using Tempu-Ring in Women of Childbearing Age (Webster – PI)  
Prima Temp, Inc. (PT-001)  
This study is a proof-of-concept to test body temperature using vaginal ring technology.  
Total funding: \$34,694  
Role: Site PI
- 2015-2016 Phase III, Single Arm, Clinical Trial To Study The Contraceptive Efficacy And Safety Of The MK-8342B (etonogestrel + 17 $\beta$ -estradiol) Vaginal Ring In Healthy Women 18 Years Of Age And Older, At Risk For Pregnancy (Fox – PI)  
Merck, Sharp and Dohme Corp. (MK-8342B-061-0035)  
This study is a Phase III trial to test the efficacy of etonogestrel + 17 $\beta$ -estradiol contraceptive vaginal ring among women at risk of pregnancy.  
Total funding: \$97,784  
Role: Site PI
- 2013-2015 How well are contraceptive guidelines followed? (Godfrey – PI)  
University of Washington Institute of Translational Health Sciences (UL 1 RR 025014)  
Small Pilot Project Grant  
Total costs: \$15,000 (research support only)
- 2013-2015 CDC Intergovernmental Personnel Agreement (IPA) (#1303027)  
Funds the development of national and global evidence-based contraceptive guidelines.  
Total funded: \$85,165
- 2006-2010 University of Illinois at Chicago, Family Planning Training Grant for Family Medicine (Godfrey – PI)  
RHEDI Program  
To train Family Medicine residents in the provision of contraception and early abortion services.  
Annual Direct Funding: \$120,000
- 2008-2010 Women's Abortion Experiences in the Family Medicine Setting (Wu – PI)  
IPAS  
To explore women's experiences of receiving abortion care in a primary care setting  
Total funding: \$30,000 (research support only)  
Role: Co-Investigator
- 2008-2009 Acceptability of the Nuvaring among College and Graduate Students (Gilliam – PI)  
Organon, Inc (Investigator Initiated Project)  
Randomized trial to compare oral contraceptive pills to the Nuvaring among university students.  
Total funding: \$18,900 (research support only)  
Role: Co-Investigator
- 2007-2009 Intrauterine Contraception for Adolescents aged 14 to 18: A pilot, multicenter, randomized controlled trial of Levonorgestrel-releasing intrauterine system compared to

Copper T 380A (Mammel – PI)

Anonymous foundation

To assess continuation, expulsions, pregnancies, and satisfaction among teens assigned to one of two forms of intrauterine devices approved by the United States FDA.

Total funding: \$69,466

Role: Co-Investigator

2006-2007 Integration of Early Abortion Services in Primary Care: Acceptability Survey of Family Medicine in Two Clinical Settings (Rubin - PI)

Center for Reproductive Health Education in Family Medicine

To determine the acceptability of early abortion services within primary care by women of reproductive age.

Total funding: \$6,200 (research support only)

Role: Co-Investigator

2001-2003 Factors Influencing Contraception Use in Women Aged 35 and Over (Godfrey – PI)

Anonymous foundation

To determine barriers to contraceptive use by women aged 35 years and older.

Total funding: \$10,500 (research support only)

### ***Completed Consultant Work***

2018-2020 Sexual and Reproductive Health in Adult Women with CF (Kazmerski – PI)

Cystic Fibrosis Foundation Career Development Award

This survey study identifies the general and disease-specific SRH concerns, care utilization, and preferences of adult women with CF. Findings will also characterize the perceived effects of sex hormones over the female life course.

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50. Miller M, Lindley A, West J, Thayer EK, **Godfrey EM**. Lower use of academic affiliation by university faculty who study abortion in top U.S. newspapers. *J Commun Healthc* DOI: [10.1080/17538068.2022.2150166](https://doi.org/10.1080/17538068.2022.2150166)
51. Lindley A, **Godfrey EM**, McClintock AH. Supporting Women in Academia: A Dyad Mentorship Model. Medical Education (in press Feb 2023).

#### b) Collaborative Authorship

1. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: adapted from the World Health Organization selected practice recommendations for contraceptive use, 2nd edition. (**EM Godfrey** CDC presenter and author) *MMWR Recomm Rep*, 2013. 62 (RR-05): p. 1-60.
2. Gavin L, Moskosky S, Carter M, Curtis K, Glass E, **Godfrey EM**, Marcell A, Mautone-Smith N, Pazol K, Tepper N, Zapata L. Providing Family Planning Services: Recommendations of CDC and U.S. Office of Population Affairs. *MMWR Recomm Rep*. 2014 Apr 25;63 (RR-04):1-54. PMID: 24759690.
3. NEJM Knowledge+ Family Medicine Board Review. Authored 9 questions with other UW DFM faculty in Obstetrics Management for comprehensive lifelong learning product from NEJM Group, 2015 (available at: <http://knowledgeplus.nejm.org/our-products/family-medicine-board-review/>).
4. World Health Organization. Brief Sexuality-Related Communication: Recommendations for a public health approach. (**EM Godfrey**, Guideline Development Group Member) 2015 (available at: [http://www.who.int/reproductivehealth/publications/sexual\\_health/sexuality-related-communication/en/](http://www.who.int/reproductivehealth/publications/sexual_health/sexuality-related-communication/en/)).

#### c) Peer-reviewed Curricula

1. **Godfrey EM**, Lossy P, Leeman L. New approaches for management of 1st trimester pregnancy complications in the Family Medicine residency setting. Family Medicine Digital Resources Library; 2006. Available from: <http://www.fmdrl.org/630>.
2. **Godfrey EM**, Devens M. Options counseling for precepting faculty slide presentation. Family Medicine Digital Resources Library; 2008. Available from: <http://www.fmdrl.org/1787>.
3. **Godfrey EM**. Resource list for implementing a basic course in early obstetrical ultrasound in the Family Medicine residency program. Family Medicine Digital Resources Library; 2008. Available from: <http://www.fmdrl.org/1841>.

**d) Book Chapters**

1. Leeman L, **Godfrey EM**. Pregnancy Termination: First Trimester Suction Aspiration. In *Pfenninger and Fowler's Procedures for Primary Care*, 3<sup>rd</sup> Edition, Ed. JL Pfenninger, GC Fowler. Philadelphia: Elsevier, 2011.
2. **Godfrey EM**, Kottke M. Contraception: Oral Contraception. In *Practical Pediatric and Adolescent Gynecology*, 1<sup>st</sup> Ed. PJ Adams Hillard. Oxford: Wiley-Blackwell, 2013.
3. **Godfrey EM**, Dehlendorf C. Integrating sexual and reproductive healthcare training into family medicine. In *Medical Education in Sexual and Reproductive Health: A systems approach in family planning and abortion*, 1<sup>st</sup> Ed. U Landy, PD Darney and J Steinauer eds. Cambridge University Press, 2021.

**e) Published Books, Videos, Software**

1. **Godfrey EM**, Gilmore K, Callegari L. [Hormonal IUD Anticipatory Guidance Video](#). University of Washington, May 2017.
2. Fiastro A, Wells E, Coeytaux F, **Godfrey E**. ACCESS, DELIVERED: A Toolkit for Providers Offering Medication Abortion. University of Washington ResearchWorks. <https://doi.org/10.6069/gad7-z583>. Published 2021. Impact: highlighted in Ms. Magazine [How Telemedicine Startups Are Revolutionizing Abortion Health Care in the U.S.](#), November 16, 2020.
3. **Godfrey EM**, Pam M, Rattiliff B, Ruben M, Al Achkar M, & Training Manual Community Advisory Board. Patient-Centered Outcomes Research Training Manual: Helping researchers initiate and maintain patient-engaged research teams (Cystic Fibrosis case study). University of Washington Department of Family Medicine, 2021. <https://doi.org/10.6069/Y2BV-YW94>.
4. **Godfrey EM**, Al Achkar, M., Thayer, E., Ruben, M., Rattiliff, B., Pam, M., Mentch, L., Brown, G., & Kazmerski, T. Workspace for Online Patient Engagement in Research. University of Washington Department of Family Medicine, 2022. <https://doi.org/10.6069/VGZR-6N29>.

**f) Other Publications**

1. **Godfrey EM**, Schaff EA. 200 mg mifepristone plus gemeprost was as effective as 600 mg for termination of pregnancy at 57-63 days gestation (commentary). *Evidence-based Obstet Gynecol*. 2003;3 (4):196-97.
2. **Godfrey EM**, Stanwood NL. Termination of early pregnancy with vaginal misoprostol alone is not as effective as with mifepristone plus misoprostol (commentary). *Evidence-based Obstet Gynecol*. 2005;5 (1):18-19.
3. Shulman LP, Bateman LH, Creinin MD, Cullins VE, Doyle LL, **Godfrey E**, Murphy P, Rodriguez P, Spear SJ, Steward FH, Thomas MA, Westhoff CL, Worthington S. Surrogate markers, emboldened and boxed warnings, and an expanding culture of misinformation: Evidence-based clinical science should guide FDA decision making about product labeling (editorial). *Contraception*. 2006;73 (5):440-42.
4. **Godfrey EM**, Schaff EA. Low-dose mifepristone and two regimens of levonorgestrel for emergency contraception: A WHO multicentre randomised trial, and randomized double-blind comparison of two single



- doses of mifepristone for emergency contraception (commentary). *Evidence-based Obstet Gynecol.* 2006;6 (1):24-26.
5. **Godfrey EM**, Spear SJ. Issues with the patch: Addressing the risks vs. benefits. (review) *Female Patient.* 2007; 32(Nov).
  6. **Godfrey EM**. Chicago protects infants by banning BPA (letter). Chicago Tribune, May 28, 2009. Accessed at [http://www.chicagotribune.com/news/opinion/letters/chi-090528godfrey\\_briefs,0,6633295.story](http://www.chicagotribune.com/news/opinion/letters/chi-090528godfrey_briefs,0,6633295.story).
  7. Jordan B, **Godfrey EM**, Espey E. Improving patient care and reducing unintended pregnancy: Translating new guidelines into effective practice. (editorial) *Contraception.* 2010; 82 (1):1-2.
  8. **Godfrey EM**. Parental notification is harmful to girls (letter). Chicago Tribune, May 14, 2010. Accessed at [http://www.chicagotribune.com/news/opinion/letters/chi-100514godfrey\\_briefs,0,7756596.story](http://www.chicagotribune.com/news/opinion/letters/chi-100514godfrey_briefs,0,7756596.story).
  9. **Godfrey EM**. Strategies to expand contraception coverage: another tool in the box. (commentary) *Contraception.* 2011; 84(4):339-341.
  10. Folger SG, Jamieson D, **Godfrey EM**, Zapata LB, Curtis KM. Evidence-based guidance on selected practice recommendations: Identification of research gaps. (commentary) *Contraception* 2013;87(5): 517-523.
  11. Sufian S, Mentch L and **Godfrey EM**. Women with CF are Helping Guide Reproductive and Sexual Health Research. *CF Roundtable: A newsletter for adults who have Cystic Fibrosis*, Summer 2017; 27(3): 16-17, 28.
  12. Harper D, **Godfrey EM**. Optimizing Women's Health in Primary Care Preface. *Primary Care* Dec 2018; 45(4):VIII-IX.
  13. Mentch L, Pam M, **Godfrey E**. Patient-Centered Outcomes Research: A new approach for the CF community. *CF Roundtable: A newsletter for adults who have Cystic Fibrosis*, Summer 2020.
  14. Agarwal M, Lindley A, **Godfrey E**. The Trump Administration is systematically undermining women's reproductive rights. [Kevin MD Blog](#)-Post, September 14, 2020.
  15. **Godfrey E**. Abortion is a health care issue, not a legal one—Allow pills by mail. [The Seattle Times Op-Ed](#), May 25, 2021.
  16. **Godfrey EM**. Yes, its easier to get birth control than it was in the 1970s - but women still need abortion care. [The Conversation](#), January 18, 2022.
  17. Riley T, Zia Y, **Godfrey E**. Our bodily autonomy is a human right, abortion is essential healthcare. The [Seattle Times Op-Ed](#), May 10, 2022.
  18. **Godfrey EM**, McClintock A. How primary care is poised to support reproductive health and abortion in the post-Roe era. [The Conversation](#), August 11, 2022.

#### g) *Manuscripts Submitted*

1. **Godfrey EM**, Schwartz MR, Hinckley-Stukovsky KD, Woodward D, Magaret AS, Aitken ML. Electronic survey piloting process as a model for developing and testing past contraceptive use and pregnancy history: Cystic fibrosis case study. Submitted to *JMIR Formative Research* (Feb 9, 2023).
2. Riley T, **Godfrey EM**, Angelini E, Zia Y, Balkus JE. Demand for medication abortion among public university students in Washington. Submitted to *J. Coll Health* (Jan, 2023).
3. **Godfrey EM**, Fiastro AE, Ruben MR, Young, EV, Bennett IM, Jacob-Files E. Patient perspectives regarding provider communication during telemedicine versus in-clinic abortion. Resubmitted to *Obstet Gynecol* (Feb 16, 2023).
4. Fiastro AE, Zheng Z, Ruben MR, Gipson J, **Godfrey EM**. Patient characteristics associated with receiving telehealth versus in-clinic medication abortion services from a high-volume reproductive health clinic. Resubmitted to *JAMA Open*, Feb 15 2023.
5. Fiastro AE, Young EV, Jacob-Files E, Ruben MR, Coeytaux FM, Bennett IM, **Godfrey EM**. Advanced provision of medication for induced abortion: A qualitative study of patient perspectives. Submitted to *Contraception* on Dec 9, 2022.

6. Sufian S, Mueller R, Ruben MR, Brown G, Schwind EL, Walker P, Mody S, Caldwell K, **Godfrey EM**. Understanding the complex embodiment of women with chronic illness: the case of cystic fibrosis. Submitted to *Sociology and Health* on Jan 29, 2023.

**h) Published Abstracts (last 5 years)**

1. **Godfrey EM**, Gilmore KC, Benson L. A novel anticipatory counseling video for new levonorgestrel intrauterine system (LNG-IUS) uses: a multicenter randomized controlled pilot study. Poster presented at the 2017 North American Forum for Family Planning. *Contraception*. 2017;96(4):280.
2. Kazmerski TM, Josephy T, Sufian S, Gilmore KC, Jain R, Ladores SL, Mody S, Heltshe S, **Godfrey EM**. Advancing comprehensive care through the interdisciplinary cystic fibrosis reproductive and sexual health collaborative. *Pediatr Pulmonol*. 2017;52(47): S481.
3. Kazmerski TM, Ladores SL, Jain R, Mody S, Pam M, Brown G, Sufian S, Mentch L, Berhalter-Tumiel L, Gilmore KC, **Godfrey EM**. The Cystic Fibrosis Reproductive & Sexual Health Collaborative: Next steps in building a sustainable partnership. *Pediatr Pulmonol*. Sep 2018;53: 412-412.
4. **Godfrey EM**, Mody S, Gilmore KC, Schwartz M, Taylor-Cousar JL, Jain R, Aitken ML, Heltshe S, Sufian S. Contraception, pregnancy and modulator use among reproductive-aged women with cystic fibrosis. *Pediatr Pulmonol*. Sep 2018;53: 420-420.
5. **Godfrey EM**, Kazmerski TM, Thayer E, Brown G, Mentch L, Pam M, Al-Achkar M. Determining the needs and content of a patient-centered outcomes research training program for the cystic fibrosis community. *Pediatr Pulmonol*. Sep 2019; 54(S2):462.
6. **Godfrey EM**, Thayer E, Mentch L, Al-Achkar M, Kazmerski TM, Brown G, Pam M. Developing an effective training program to build patient-centered outcomes research (PCOR) capacity within the cystic fibrosis community. *Pediatr Pulmonol*. Sep 2019; 54(S2):209.
7. **Godfrey EM**, Schwartz M, Thayer E, Woodward D, Stukovsky KH, Aitken ML. Collecting contraceptive history among women with cystic fibrosis: Pilot testing survey questions. *Pediatr Pulmonol*. Oct 2020 vol 55(S2):S329.
8. Kazmerski TM, Stransky OM, Taylor-Cousar JL, Sawicki GS, Ladores SL, **Godfrey EM**, Aitken ML, Sufian S, Jain M, Barto TL, Billins J, Hadjiliadis D, Jain R. Sexual and reproductive health care utilization and preferences of adult women with cystic fibrosis. *Pediatr Pulmonol*. Oct 2020; 55 S95.
9. Kazmerski TM, Stransky OM, Taylor-Cousar JL, Sawicki GS, Ladores SL, Godfrey EM, Aitken ML, Sufian S, Jain M, Barto TL, Billings J, Hadjiliadis D, Jain R. Sexual and reproductive health behaviors and experiences of adult women with cystic fibrosis. *Pediatr Pulmonol*. Oct 2020; 55:S91.
10. Nguyen AN, Tan N, **Godfrey E**, McClintock AH. Faith-based and federal government-affiliated training sites for primary care: Implications for Women's health services. *J Investig Med*. Jan 2021; 69(1):244.
11. Ruben M, **Godfrey E**, Rattiliff B, Brown G, Caldwell K, Mody S, Langfelder-Schwind E, Walker P, Sufian S. Factors contributing to success retention of people with cystic fibrosis in a 3-month daily symptom-tracking study. *J Cyst Fibros* 21S2 (2022): S18.
12. Mody S, Sufian S, Ruben M, Caldwell K, Walter P, Langfelder-Schwind E, Brown G, **Godfrey E**. Feasibility of using a modified menstrual tracking app to correlate menstrual cycles and cystic fibrosis symptoms in women with CF: Early findings of the MENSTRUAL study. *J Cyst Fibros* 21S2 (2022): S14.
13. **Godfrey EM**, Fiastro A, Ruben M, Young E, Bennett IM, Jacob-Files E. Determining best communication practices in telemedicine abortion care: Qualitative study of patient perspectives. *Ann Fam Med*. Jan 2023, 21 (Supp 1) 4114. DOI: <https://doi.org/10.1370/afm.21.s1.4114>

## 18. Invited Lectures

### *Invited National and International Lectures*

Emily M. Godfrey, MD MPH

Feb 2023

- 2001 “Medical abortion: Indications for use.” 8<sup>th</sup> Annual Medical Students for Choice National Meeting, April, Chicago, IL
- 2002 “Medical abortion.” 9<sup>th</sup> Annual Medical Students for Choice National Meeting, April, San Jose, CA
- 2002 “Treatment of spontaneous abortion with misoprostol.” Annual Meeting of the Nicaraguan Society of Obstetricians and Gynecologists, July, Managua, Nicaragua.
- 2002 “The uses of medications in spontaneous abortion: Misoprostol.” International Family Planning Leadership Program at the University of California, San Francisco Center for Reproductive Health and Policy, September, San Francisco, CA
- 2004 “Advanced gynecological procedures.” 32<sup>nd</sup> Annual Conference of the American Association of Physician Assistants, June, Las Vegas, NV.
- 2005 “Update on intrauterine contraception: Lecture and workshop.” 17<sup>th</sup> Annual Meeting of Contraceptive Technology, April, Washington DC
- 2005 “Manual vacuum aspiration workshop.” Planned Parenthood Federation of America, June, Philadelphia, PA.
- 2005 “IUD insertion workshop.” Contraceptive Technology: Quest for Excellence, October, Atlanta, GA.
- 2005 **Plenary talk** “Menstrual suppression and flexible contraceptive options.” Contraceptive Technology: Quest for Excellence, October, Atlanta, GA.
- 2006 “Manual vacuum aspiration workshop.” Nurse Practitioner Meeting of the Planned Parenthood Federation of America, February, Philadelphia, PA.
- 2006 “Medical Students for Choice provider panel.” Annual Meeting of the American Medical Students Association National Conference, April, Chicago, IL.
- 2006 “Options for managing early pregnancy loss: Focus on manual vacuum aspiration workshop.” Annual Meeting of the Association of Reproductive Health Professionals, September, La Jolla, CA.
- 2007 “Management of early pregnancy failure in the outpatient or emergency department setting.” Association of Reproductive Health Professionals National Webinar Series, April 11 and July 11
- 2008 “Options for therapeutic abortion: Manual vacuum aspiration and medication management.” Association of Reproductive Health Professionals National Webinar Series, March 12.
- 2008 **Presenter and Panelist**, Junior faculty career development and research panel. Association of Reproductive Health Professionals 45<sup>th</sup> Annual Conference, Washington DC.
- 2008 **Presenter and Panelist**, Psychosocial components of complication management. Panel Discussion for the 2<sup>nd</sup> Annual Psychosocial Conference for the Fellowship in Family Planning. San Francisco, CA.
- 2010 “Medical management of early pregnancy loss.” Association of Reproductive Health Professionals National Webinar Series, January 11.
- 2010 “Medical management of early pregnancy loss.” Annual Conference of the Association of Reproductive Health Professionals/Society of Family Planning, September, Atlanta, GA.
- 2010 **Presenter and Panelist**, “How Research Guides Clinical Practice.” Annual Conference of the Association of Reproductive Health Professionals/Society of Family Planning, September, Atlanta, GA.
- 2011 “The United States Medical Eligibility Criteria and World-wide Updates for Contraception Use in Adolescents.” 25<sup>th</sup> Annual Meeting of the North American Society for Pediatric and Adolescent Gynecology, April, Chicago, IL
- 2011 “Contraceptive Update: CDC Medical Eligibility Criteria for Women with Certain Characteristics and Medical Conditions.” Association of Reproductive Health Professionals National Webinar Series, May.
- 2011 **Presenter and Panelist**, “The Impact of Chronic Medical conditions on Reproductive Health Module.” 48<sup>th</sup> Annual Conference of the Association of Reproductive Health Professionals, September, Las Vegas, NV.

- 2011 **Presenter and Panelist**, “Contraceptives for Women with Chronic Conditions: A panel presentation.” North American Forum on Family Planning, October, Washington, DC.
- 2011 “Contraception Updates from the CDC.” Contraceptive Technology: Quest for Excellence, November, Atlanta, GA.
- 2011 “Using Society of Family Planning and Centers for Disease Control and Prevention Guidelines to Improve Patient Care.” Medical Students for Choice Annual Meeting, November, Baltimore, MD.
- 2012 “The New U.S. Selected Practice Recommendations: Practical Applications for Contraceptive Management.” Contraceptive Technology Annual Conferences, March, San Francisco, CA and Boston, MA.
- 2012 “Male Patients in the Family Planning Clinic: Clinical Cases.” Contraceptive Technology Annual Conferences, March, San Francisco, CA and Boston, MA.
- 2013 “Update on the New U.S. Selected Practice Recommendations.” Contraceptive Technology Annual Conference, March, San Francisco, CA.
- 2013 “Contraceptive cases utilizing the new U.S. Selected Practice Recommendations for Contraceptive Use.” Contraceptive Technology Annual Conference, March, San Francisco, CA.
- 2014 **Plenary**, “Highlights of the U.S. Selected Practice Recommendations (SPR).” Contraceptive Technology Annual Conference, March/April. San Francisco, CA and Boston, MA.
- 2014 “Utilizing the New U.S. Selected Practice Recommendations for Contraceptive Management: Interesting cases.” Contraceptive Technology Annual Conference, San Francisco, CA and Boston, MA.
- 2016 “Evidence-based Family Planning Care: Incorporating National Guidelines into Your Practice.” Contraceptive Technology Annual Conference, March/April. San Francisco CA and Boston, MA.
- 2017 **Feature Presentation**, “Just Out! The updated 2016 contraceptive guidelines from the Centers for Disease Control and Prevention.” Society of Adolescent Health and Medicine National Conference, March. New Orleans, LA.
- 2018 “Vision and Persistence: A clinician’s journey to patient engaged research, Northern New England Clinical & Translational Research Network (NNE-CTR), June 10, Portland, ME.
- 2019 Creating a relationship with your women’s healthcare provider. Cystic Fibrosis Reproductive and Sexual Health Collaborative (VIRTUAL).
- 2020 Contraceptive care for patients with cystic fibrosis. Cystic Fibrosis Reproductive and Sexual Health Collaborative (VIRTUAL).
- 2020 **Presenter and Panelist**, “Virtual Engagement. Presented with patient-partner at the June 24 [PCORI Engagement Award Lunch and Learn](#).”
- 2020 “Contraception in the era of CFTR modulators.” Presented with clinician- and patient- partners at the July 22 [CFRI Townhall](#).
- 2020 **Keynote Speaker**, “Best Practices for Virtual PCOR Engagement.” NAPCRG Patient and Clinician Engagement (PaCE) Preconference, November 19.
- 2020 **Presenter and Panelist**, “Access, Delivered Project” through the Introduction to the Changing Landscape of Medication Abortion. at Reproductive Health Access Project (RHAP)-sponsored event. (virtual event), October and December.
- 2021 **Presenter**, “CF Symptoms and the Menstrual Cycle.” North American Cystic Fibrosis Conference Hot Topics and Trends in Clinical Research (virtual event), November 5
- 2021 **Presenter and Panelist**, “Navigating PCORI as a Family Planning Researcher.” Society of Family Planning (virtual event), November 9.
- 2022 **Presenter and Panelist**, “Better Health NOW: Online Public Launch of Primary Care Collaborative to address health inequities and lack of access to whole-person care.” Primary Care Collaborative (virtual event), March 29.
- 2022 **Presenter and Panelist**, “World Contraception Day Webinar” Upstream USA (virtual event), September 26.



2022 **Presenter and Panelist**, “NAPCRG Diamonds – Patient and Clinician Session” 2022 NAPCRG Annual Conference, Phoenix AZ, Nov. 22.

***Invited Regional Lectures***

2002 **Grand Rounds**, University of Wisconsin-Madison Dept. of Family Medicine “Medical abortion regimens.” July, Madison, WI.

2002 **Grand Rounds**, Medical College of Ohio Dept. of Obstetrics and Gynecology. “Medical abortion basics.” December, Toledo, OH.

2003 **Grand Rounds**, Stroger Hospital of Cook County Dept. of Obstetrics and Gynecology “Medical abortion basics.” June, Chicago, IL.

2004 “Update on intrauterine contraception.” Workshop presented at the Nurse Practitioner Regional Conference, September, Chicago, IL.

2004 **Grand Rounds**, Swedish American Hospital Dept. of Obstetrics and Gynecology, “Update on intrauterine contraceptive methods.” December, Rockford, IL.

2005 **Grand Rounds**, Illinois Masonic Medical Center Medical abortion from the primary care perspective. Grand Rounds lecture presented to the Department of Family Medicine, , Chicago, IL.

2005 “Update on intrauterine contraception.” Workshop presented to the Knoxville Public Health Department, Knoxville, TN.

2005 “Manual vacuum aspiration: Practicing with papayas.” Workshop presented to public health students, Abortion Access Project National Meeting, Chicago, IL.

2005 **Grand Rounds**, “Manual vacuum aspiration”. Grand Rounds lecture presented to the Department of Obstetrics and Gynecology, Stroger Hospital of Cook County, Chicago, IL.

2006 **Grand Rounds**, Menstrual suppression and flexible contraceptive options. Grand Rounds lecture presented to the Department of Family Medicine, University of New Mexico, Albuquerque, NM.

2006 **Grand Rounds**, Update on intrauterine contraception: How the OB/GYN can play a role. Grand Rounds lecture presented to the Department of Obstetrics and Gynecology, Rush Medical College, Chicago, IL.

2006 “Medical abortion from a public health perspective.” Lecture presented to medical students, Northwestern University Medical Students for Choice and American Medical Student Association, Chicago, IL.

2007 **Panelist**, “Abortion providers: Safety panel”. Roundtable presented at the 1<sup>st</sup> Annual Meeting of the Psychosocial Conference for the Fellowship in Family Planning. San Francisco, CA.

2007 “Intrauterine device skills seminar”. Workshop, tutorial and patient training presented for Region V Title X Nurse Practice Clinicians Meeting, South Bend, IN.

2007 **Grand Rounds**, “Cases in contraception.” Grand Rounds lecture presented to the Department of Family Medicine, UIC-Rockford, Rockford, IL.

2009 **Presenter and Panelist**, “The Gaping Hole in the Closing Gap: Women in Academic Medicine.” American Medical Women’s Association Region 6 Conference and Research Symposium, Chicago, IL.

2010 “Providing in non-urban settings.” Lecture-Discussion presented at Midwest Region 5 Medical Students for Choice Conference, Chicago, IL.

2010 “Office-based miscarriage management.” Midwest Access Project Reproductive Health Seminar Series for Family Medicine Physicians, Chicago, IL.

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- 2013 “Combined Hormonal Contraceptives and Perimenopause: Management Strategies for a Smoother Transition.” University of Washington Department of Obstetrics and Gynecology Women’s Health Care Update CME Course, Seattle, WA.
- 2013 “Adolescent Women’s Healthcare: STIs, contraception and pregnancy.” Washington Academy of Family Physicians 64<sup>th</sup> Annual Scientific Assembly, Cle Elum, WA.
- 2013 “Contraceptive Updates and Recommendations.” University of Washington Maternal Child Health Public Health Webinar, Seattle, WA.
- 2013 “Reproductive Sexual Health (STDs, Contraception and Unplanned Pregnancy): Using clinical cases and guideline tools.” University of Washington Department of Family Medicine 41<sup>st</sup> Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.
- 2013 “Venous Thromboembolism: Is there a risk with progestins?” Advance Practice in Primary and Acute Care 36<sup>th</sup> Annual CME Course, Seattle, WA.
- 2013 “Contraception for Women with Medical Conditions”. University of Washington Department of Family Medicine 41<sup>st</sup> Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.
- 2013 “Contraceptive Updates and Recommendations from the CDC.” Planned Parenthood Great Northwest Clinical Advisory Meeting, Seattle, WA.
- 2014 “Contraceptive-Antiretroviral Drug Interactions: Issues to consider when prescribing contraceptives to HIV+ patients.” Northwest AIDS Education and Training Center Clinical Update, Seattle, WA.
- 2014 “Complex Contraceptive Cases: Guidance from the CDC”. University of Washington Department of Family Medicine 42<sup>nd</sup> Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.
- 2015 “Complex Contraception: Using National Guidance to Find Answers.” University of Washington Department of Family Medicine 43<sup>rd</sup> Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.
- 2015 “Contraceptive Dilemmas: Finding Solutions Using the US Medical Eligibility Criteria and Selected Practice Recommendations.” Advanced Practice in Primary and Acute Care 38<sup>th</sup> Annual CME Course, Seattle, WA.
- 2016 “How well are contraceptive guidelines followed?” WWAMI-region Practice and Research Network Annual Meeting, Seattle, WA.
- 2016 “Updates on the United States Medical Eligibility Criteria for Contraceptive Use and the Selected Practice Recommendations for Contraceptive Use.” Advanced Practice in Primary and Acute Care 39<sup>th</sup> Annual CME Course, Seattle, WA.
- 2017 “Treatment of Menopausal Symptoms.” Current Concepts in Drug Therapy CME Course, University of Washington Department of Medicine, Seattle, WA.
- 2017 “Treatment of Menopausal Symptoms.” University of Washington Department of Family Medicine 45<sup>th</sup> Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.
- 2017 “Demystifying contraception for the medically complex patient.” Advanced Practice in Primary and Acute Care 40<sup>th</sup> Annual CME Course, Seattle, WA.
- 2018 “What to expect when you don’t want to expect: Development of anticipatory counseling video for hormone IUD users.” UW Friday Harbor Lab, Friday Harbor, WA.
- 2018 “Advances in Contraception: Uses in Young Women and Perimenopausal Women.” Advanced Practice in Primary and Acute Care 41<sup>st</sup> Annual CME Course, Seattle, WA.
- 2020 **Presenter and Panelist**, “Engaging our communities in research.” Pacific Northwest Family Planning Symposium, Honolulu, HI.

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- 2020 “Contraception across the gender spectrum.” Advanced Practice in Primary and Acute Care 43<sup>rd</sup> Annual CME Course, (VIRTUAL).
- 2021 “Depo-medroxyprogesterone acetate (DMPA) and Bone Health” University of New Mexico Dept. of Obstetrics and Gynecology ECHO Project, Jan. 11 (VIRTUAL).
- 2021 “Access, Delivered: A toolkit for providers to implement telehealth medication abortion services.” UW WWAMI Region Practice-based Research Network Annual Conference, New Investigator Session Mar. 4 (VIRTUAL).
- 2022 **Presenter and Panelist** “Family medicine and medication abortion.” King County Academy of Family Physicians, Nov. 3 (VIRTUAL).

***Invited Local Lectures***

- 2004 “Clinical update on the copper T IUD.” University of Chicago Obstetrics and Gynecology Residency, November, Chicago, IL.
- 2006 “Flexible contraceptive options.” Lecture presented to Obstetrics and Gynecology residents, University of Chicago, Chicago, IL.
- 2008 “Public health importance of family planning.” Lecture presented to 1st and 2nd year medical students for the Family Planning Elective. University of Chicago Pritzker School of Medicine, Chicago, IL.
- 2008 “Long-term progestin contraceptive methods.” Workshop lecture presented to residents in the Department of Obstetric and Gynecology, Loyola University of Chicago, Chicago, IL.
- 2010 **Grand Rounds**, University of Illinois at Chicago Dept. of Family Medicine. “The United States CDC Medical Eligibility Criteria for Women with Medical Conditions.” Chicago, IL.
- 2010 “Physician decision making regarding morally/bioethically controversial procedures.” Northwestern University Medical School Profession of Medicine course for 2<sup>nd</sup> year medical students, Chicago, IL.
- 2010 “Understanding the US Medical Eligibility Criteria for Women with Medical Conditions from a Public Health Perspective.” Emory University School of Public Health, Atlanta, GA.
- 2011 “Using the US Medical Eligibility Criteria for Contraception Use for Women with Medical Conditions.” Emory University School of Medicine, Department of Gynecology and Obstetrics Family Planning lecture series, Atlanta, GA.
- 2011 “Understanding the US Medical Eligibility Criteria for Women with Medical Conditions from a Public Health Perspective.” Emory University School of Public Health, Atlanta, GA.
- 2011 **Grand Rounds**, Emory University School of Medicine, Dept of Gynecology and Obstetrics, “Updates from the CDC: Translating Research to Practice for Contraceptive Use.” Atlanta, GA.
- 2012 “Contraception: Using U.S.-based Guidelines to Help Prevent Unplanned Pregnancy.” Emergency Medicine Resident Lecture. Veterans Administration Hospital, Atlanta, GA.
- 2012 “Contraception Basics for Internal Medicine.” Internal Medicine Resident Lecture. Veterans Administration Hospital, Atlanta, GA.
- 2013 “Breaking Bad News: Fetal Anomalies and Fetal Demise.” University of Washington Department of Radiology Fellowship Seminar, Seattle, WA.
- 2014 “CDC Family Planning Guidance.” UW Center for Research in Reproduction and Contraception, Seattle, WA.
- 2015 “Anticipatory Counseling on LNG IUS Continuation, Utilization and Satisfaction ACCCUSS Study.” University of Washington Department of Obstetrics and Gynecology Faculty Research Seminar, Seattle, WA.
- 2015 “Developing quality, evidence-based family planning tools and guidelines.” University of Washington Department of Global Health spring course GH 490/590,

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Feb 2023

- Seattle, WA.
- 2015 “Hormonal and non-hormonal Contraceptive Lecture”, University of Washington MEDEX Program, Seattle WA.
- 2017 “Zika: CDC Emergency Relief Efforts in Puerto Rico and what the Seattle family physician needs to know,” UW Department of Family Medicine Grand Rounds, Seattle, WA.
- 2017 “Zika and women of reproductive age-mastering intervention on the global stage,” UW Department of Obstetrics and Gynecology Resident Seminar, Seattle, WA.
- 2017 “Case study of Zika.” UW Global Health Department, Global Perspectives in Reproductive Health Course, Seattle, WA.
- 2019 “Patient-centered outcomes research.” UW Dept. of Family Medicine Residency lecture, Seattle WA.
- 2019 “Best practices for online engagement for patient-centered outcomes research teams: work in progress”. UW Dept. of Family Medicine Research Section seminar, Seattle, WA.
- 2020 “A Stepwise Process to Strengthen Surveys Asking About Prior Contraceptive Use.” UW Dept. of Family Medicine Research Section seminar (VIRTUAL)
- 2021 “Upstream USA: Implementing comprehensive contraceptive care into primary care.” UWNC Clinic Chief Meeting Jan. 13 (VIRTUAL).
- 2021 “Scholarship mentorship in residency: a triad model.” UW Dept. of Family Medicine Residency Program, Feb. 22, 2021. Presented with colleague Dr. Alexa Lindley. (VIRTUAL).
- 2021 “The Updated 2016 Contraceptive Guidelines from the Centers for Disease Control and Prevention (CDC).” UW Complex Family Planning Fellowship, Dept of Obstetrics and Gynecology, Mar. 9 (VIRTUAL).
- 2022 “Clinical operations of providing telehealth medication abortion services for family medicine clinicians working in diverse settings.” Research Seminar, Dept of Family Medicine, Jan. 4 (VIRTUAL).
- 2022 **Presenter and Panelist** “Impact of shifts in U.S. law and policy on health care practice and health services research.” HSPop fall seminar, UW School of Public Health, Nov. 16 (VIRTUAL)
- 2023 “I definitely felt at greater ease.” Patient perspectives of telemedicine versus in-clinic abortion care. Research Seminar, Dept of Family Medicine, Jan. 3 (VIRTUAL).

# Exhibit 9

1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
Civil Rights Division Chief  
5 ANDREW R.W. HUGHES, WSBA #49515  
LAURYN K. FRAAS, WSBA #53238  
6 Assistant Attorneys General  
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8 800 Fifth Avenue, Suite 2000  
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9 (206) 464-7744

10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
MARJI GOLD, MD

1 I, Marji Gold, declares as follows:

2 1. I am over the age of 18. I make this declaration based on my own  
3 personal knowledge and am competent to testify as to the matters herein.

4 **A. Background and Qualifications**

5 2. I am a Board-Certified family physician in the Bronx, New York. I  
6 am also a professor in the Department of Family and Social Medicine at Albert  
7 Einstein College of Medicine.

8 3. I hold degrees from Sarah Lawrence College and NYU Medical  
9 School.

10 4. I underwent special training in abortion care and reproductive health  
11 care in the early 1980s, and have been performing abortions for approximately  
12 40 years.

13 5. I have been performing medical abortions since 1995, when I was a  
14 site director for the mifepristone clinical trials in the United States that ultimately  
15 led to the FDA's approval of mifepristone.

16 6. Since the FDA approved mifepristone in 2000, I have been offering  
17 patients medication abortion with mifepristone and misoprostol as part of my  
18 regular clinical role.

19 7. A copy of my curriculum vitae is attached hereto as Exhibit A.  
20  
21  
22

8. I submit this declaration in support of Plaintiff's Motion for Preliminary Injunction. I do so only in my individual capacity, not on behalf of any institution with which I am affiliated.

9. I have been retained as an expert in this matter, and am being compensated at a rate of \$500 per hour.

## **B. Expert Opinions**

### **1. Mifepristone's safety and efficacy is remarkable**

10. Mifepristone is one the safest, most effective medications currently prescribed in the United States. Since the initial clinical trials that I worked on in 1995, study after study has confirmed that mifepristone, when used as part of a regimen with misoprostol, is over 95% effective in successfully completing an abortion, with a rate of major adverse events of less than .6%.<sup>1</sup>

11. Mifepristone is safer than acetaminophen (Tylenol®), sildenafil (Viagra®), or just about any other commonly used medicine.

12. The most common side effects associated with medication abortions using mifepristone are nausea, cramping, and bleeding. But these are not really

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<sup>1</sup> See, e.g., Ushma D. Upadhyay, et al., *Outcomes and Safety of History-Based Screening for Medication Abortion A Retrospective Multicenter Cohort Study*, JAMA INTERN MED. 2022;182(5):482-491; ACOG Practice Bulletin 225; VOL.136, NO. 4, October 2020



1 side effects: they are expected because that is how the medicine works. Once  
2 mifepristone stops the pregnancy from developing, misoprostol stimulates  
3 uterine contractions, which expel the pregnancy from the uterus. This process is  
4 very similar to a miscarriage.

5 **2. The January 2023 REMS cannot be justified by any medical or**  
6 **safety concerns**

7 13. The U.S. Food and Drug Administration (“FDA”) has imposed a  
8 Risk Evaluation and Mitigation Strategy (“REMS”) on mifepristone. The current  
9 REMS, which went into effect in January 2023, requires that clinicians must sign  
10 a “Provider Agreement” form before they dispense or prescribe mifepristone, that  
11 pharmacists must sign a form certifying that they will dispense the medication  
12 subject to various monitoring and recordkeeping requirements, and that patients  
13 sign a Patient Agreement form. After signing the Provider Agreement, a clinician  
14 is considered certified, and similarly, after a pharmacy completes the Pharmacy  
15 Agreement form, it is considered a certified pharmacy. The REMS also state that  
16 mifepristone can only be dispensed to patients in clinic by or under the  
17 supervision of a certified prescriber, or by certified pharmacies for prescriptions  
18 issued by certified prescribers. Those updates went into effect on January 3, 2023.

19 14. From a medical and safety standpoint, these conditions are totally  
20 unnecessary. Mifepristone is extremely safe and effective, and there is no basis  
21  
22

1 for imposing burdensome conditions on mifepristone that are not required for  
2 countless other, more dangerous and less effective drugs.

3 **3. Rather than improving patient safety, the January 2023 REMS**  
4 **impedes access to mifepristone and decreases patient safety**

5 15. The January 2023 REMS fails to improve patient safety. In fact, the  
6 January 2023 REMS has the contrary effect of decreasing patient safety by  
7 making access to mifepristone more difficult, and thus increasing the time that  
8 the patient has to wait for the abortion. Generally speaking, mifepristone in  
9 combination with misoprostol is safest and most effective when used earlier in  
10 pregnancy, with the risks increasing as the pregnancy proceeds.

11 16. For instance, the requirement of the January 2023 REMS that the  
12 prescriber be certified delays patients' access to mifepristone in cases where the  
13 patient's regular physician has not completed the certification paperwork. These  
14 patients will have to locate a physician who *is* certified, and that delay can  
15 decrease patient safety as stated above. The patient may also need to miss days  
16 from work and/or school, and lose income.

17 17. Additionally, well-founded fears of harassment and violence deter  
18 providers and institutions from becoming certified. Historically, providers and  
19 institutions have been concerned about the risks associated with being on a list of  
20 abortion providers, for fear that such a list could easily be leaked, or its security  
21 otherwise compromised. It can be very dangerous to be publicly known as an  
22

1 abortion provider. In the late 1980s, for example, there were a lot of shootings of  
2 doctors and clinic staff at abortion clinics and in their homes. The high-volume  
3 abortion clinics in which I worked during that time had offered bulletproof vests  
4 for the doctors to wear. In addition, many clinics that offer abortion care have  
5 been damaged by arson; many have had to close. Harassment of abortion  
6 providers is a reality that I have personally had to contend with, and continues to  
7 impact many clinicians on a regular basis.

8 18. In the current hostile environment surrounding abortion care, which  
9 includes states passing bills that empower ordinary citizens to sue anyone they  
10 deem has “aided and abetted” a person seeking an abortion, clinicians may be  
11 reluctant to become certified and thus be identified as a person who prescribes  
12 mifepristone. Since the REMS requires certified prescribers to send their signed  
13 forms to *each* certified pharmacy at which they intend to prescribe, clinicians  
14 who wish to provide this care have reason to be concerned that an anti-abortion  
15 staff or pharmacist at a pharmacy might leak the confidential list and expose them  
16 to possible violence and/or civil or criminal liability. These concerns may be  
17 greater in communities with outspoken anti-abortion members, and thus decrease  
18 patient access to care.

19 19. Clinicians who hold medical licenses in multiple states, especially  
20 those with very restrictive and punitive abortion laws, may feel that they are  
21 likely to face criminal prosecution or litigation in those states, even if they live  
22

1 and work in a state like Washington or New York, where I live, that protects  
2 abortion services and clinicians who provide abortion care. These clinicians may  
3 be reluctant to sign the certification form even in their supportive home state. I  
4 get similar questions from the family medicine residents and students that I train,  
5 especially those who come from very restrictive states and plan to return there to  
6 work after completing their training; they wonder if “being on the mifepristone  
7 list” will put them at risk of harassment, violence, and/or prosecution if they  
8 return home to be closer to their families. By fostering these sorts of fears, the  
9 REMS certification requirement discourages providers from prescribing  
10 mifepristone, and therefore makes it more difficult for patients to obtain it.

11 20. Additionally, the requirement of the January 2023 REMS that the  
12 prescriber be certified is redundant because providers are already engaged in the  
13 practices the certification requires. That is, providers already screen for fetal age,  
14 for ectopic pregnancies, and counsel patients for every medication abortion, in  
15 accordance with standard medical practice.

16 21. In addition, clinicians who might want to be able to offer medication  
17 abortion to their patients might see the REMS-mandated certification as an  
18 indication that mifepristone is actually more dangerous than it is, and different  
19 from the other medications that we offer patients on a regular basis. These  
20 clinicians might decide not to offer this care, thus decreasing the abortion-  
21 providing workforce and creating yet another barrier to abortion access.  
22

1           22. The January 2023 REMS requirement that patients sign a specific  
2 form (the “Patient Agreement”) in order to be treated with mifepristone has the  
3 effect of making abortion or miscarriage treatment look entirely different from  
4 any other common medical treatment. Patients don’t need to sign an agreement  
5 for insulin, or blood pressure medications, or asthma medication, to name a few,  
6 to be prescribed to their preferred pharmacy; having to sign a form makes  
7 mifepristone seem more dangerous than it actually is, and may deter patients from  
8 choosing their preferred treatment for abortion. This process undermines patient  
9 autonomy. Additionally, at many clinics that serve low-income communities of  
10 color, including the clinic where I practice, the Patient Agreement form is not  
11 available electronically and only available in paper form. Thus, patients have to  
12 physically come to the office to sign the form, even though they are otherwise  
13 permitted to see a doctor remotely and receive the prescription by mail or  
14 dispensed at a pharmacy—which is a much more convenient and accessible  
15 option for many patients.

16           23. The Patient Agreement form requirement for mifepristone does not  
17 make sense from a medical or safety standpoint given that standard treatments or  
18 drugs with higher risks (such as insulin or acetaminophen [Tylenol®], for  
19 example) do not require a Patient Agreement form.

20           24. The January 2023 REMS requirement that pharmacies must be  
21 certified in order to dispense mifepristone is another requirement that impedes  
22

1 access to mifepristone. As a provider/prescriber, I find this requirement  
2 burdensome because I (or my patients) need to call around to multiple pharmacies  
3 to locate one that is certified to dispense mifepristone. This requirement of the  
4 January 2023 REMS results in mifepristone being more difficult for patients to  
5 obtain. No other drug is burdened by this same requirement that the pharmacy  
6 must be specially certified.

7 25. Additionally, the requirement of the January 2023 REMS that the  
8 pharmacy be certified is redundant because pharmacists are already engaged in  
9 the practices the certification requires. Pharmacists routinely check with patients  
10 about drug allergies, confirm that they are not taking other medications that might  
11 interact with mifepristone, and advise patients on the prescriber's instructions for  
12 use of the medicine, in accordance with standard pharmacist practice.

13 26. When I was working on the mifepristone clinical trials, and when  
14 mifepristone was subsequently approved by the FDA, there was great hope that  
15 abortion care would become widely available for everyone who needed it.  
16 Mifepristone, in theory, made it possible for family physicians, as well as other  
17 primary care clinicians, to provide abortion care as part of their routine primary  
18 care practice.

19 27. Without any scientific or medical basis, the REMS has consistently  
20 frustrated that hope and kept abortion care beyond the reach of many patients,  
21 especially those from low-income communities of color, and other groups that  
22

1 that are routinely marginalized from care. The primary care physicians who serve  
2 these communities are also disappointed that they cannot offer this routine  
3 medical service to patients in accordance with standard medical practice without  
4 becoming certified. As a result of the REMS restrictions, medication abortion  
5 has been largely relegated to specialized abortion clinics.

6  
7 I declare under penalty of perjury under the laws of the State of Washington and  
8 the United States that the foregoing is true and correct.

9 DATED this 21st day of February, 2023, at Bronx, New York.

10   
11 Marji Gold, MD

# Exhibit A



Marji Gold, M.D.

Curriculum Vitae

## **EDUCATION**

1969 Sarah Lawrence College, Bronxville, New York B.A.

1973 New York University School of Medicine, New York, N.Y. M.D.

## **POST-GRADUATE TRAINING**

### **Montefiore Medical Center**

7/73-6/76 Internship/Residency in Family Medicine

7/75-6/76 Chief Resident in Family Medicine

1982 Special training in performing first trimester abortions

7/85-7/88 Fellowship in Faculty Development in Family Medicine: Research project in collaboration with the AECOM DRTC evaluating the impact of educational intervention on provider behavior in the treatment of type II diabetics at the Montefiore Family Health Center

### **Institute for Urban Family Health**

8/83-7/85 Faculty Development Program

## **PROFESSIONAL EXPERIENCE**

### **Montefiore Medical Center**

1976-present Family Medicine Residency Program

A: Ambulatory community health center practice (at the MMG-2 Family Health Center), including prenatal and postpartum care, full child and adult health care, routine women's health care

B: Supervision and teaching of residents, medical students, and nurse practitioners at the ambulatory care site, **8 hours/week**

C: Coordinator of women's health curriculum for family medicine residents

D: Faculty advisor for "centering pregnancy" project for prenatal care at FHC

E: Advising residents (1-2/year) on social medicine projects

F: Advising/preparing residents for presentations – local and STFM

1982-present Family Medicine Residency Program Trainer in first trimester abortion procedures

2003-2022 Director, RHEDI/Center for Reproductive Health Education in Family Medicine – grant funded (\$1,000,000/year)

Marji Gold, MD

Curriculum Vitae

2

Oversee all aspects of program providing funding and technical assistance to family medicine residency programs seeking to integrate abortion and family planning training into the required curriculum. Coordinate evaluation and funding of active programs, and work with faculty at additional programs to assist them with curriculum development and implementation strategy.

Supervise and train fellows, residents, and medical students in the twice-weekly reproductive health session at the Family Health Center

Develop and present departmental grand rounds 1-2 times/year

Oversee the women's health rotation for the family medicine residents

Mentor family medicine residents (3-5/year) in project development and implementation, preparation for presentations, and overall career plans

Oversee and coordinate program for free LARC devices for FHC and WB

### **Albert Einstein College of Medicine**

1992-93 Development of curriculum for family medicine clerkship and cases for problem-based learning (PBL) seminars

1993-2005 PBL seminar leader for family medicine clerkship

1993-2005 Facilitator for special topic seminars ("Breastfeeding Promotion" and "Counseling for Reproductive Choice") during each rotation in the family medicine clerkship

1993-2004 Faculty advisor for community project (Barriers to Emergency Contraception)

Includes meetings with students during each rotation in the family medicine clerkship to help plan their project, assessing the progress of the project, reading and commenting on their final reports

1998-2004 Family medicine clerkship site director

1992- 2012 Faculty for 1<sup>st</sup> year AECOM student on ICM/Generalist Mentorship Pathway

2002-present Director of 4<sup>th</sup> year clinical elective "Reproductive Health" at FHC

2006-present Course leader for Reproductive Health unit in Research-Based Advocacy Course

2003-present Faculty Advisor, Medical Students for Choice

Includes shadowing in clinical sessions, presentations at local and regional meetings, one-on-one career advice **15 hours/month**

2004-present Faculty Mentor AMWA

Includes dinners with students, student visits to the FHC, discussions about future plans and "surviving" medical school

Marji Gold, MD

Curriculum Vitae

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1994-2001; 2002-2005

Director, HRSA-funded Faculty development Fellowship

Included weekly meetings with the fellowship group, reviewing components of successful adult education, developing and practicing presentations with feedback from the group, developing, implementing, and evaluating an educational intervention project, as well as one-on-one meetings to develop career plans

2002-present Director, Fellowship in Family Planning (grant-funded \$800,00 year)

Lead weekly meetings with the fellowship group, review components of successful adult education in reproductive health care, help fellows build skills in developing and practicing presentations with feedback from the group, developing, implementing, and evaluating a research project, writing for publication, as well as one-on-one meetings to develop career plans. **Time with fellows for clinical supervision and mentoring: 15 hours/week**

2004-Present: Director, RHEDI 9grant-fiunded, ab out \$1,000,000 annually). National director of programs to incorporate abortion training into family medicine residency programs.

2004-present: Director, Reproductive Health Clinic at Family Health Center. **Time with residents for direct supervision: 10 hours/week**

### **Planned Parenthood/NYC**

1993-present Abortion trainer in CTI (Clinician Training Initiative) program for family physicians

### **FACULTY APPOINTMENTS**

Professor, Family and Social Medicine, Albert Einstein College of Medicine

Assistant Professor, Epidemiology and Population Health, Albert Einstein College of Medicine

### **RECENT GRANTS**

**2015-17** NYC DOH Quality Improvement Network for Contraceptive Access (QINCA): NYC Hospital Learning Collaborative co-PI

**2017-19** Interest in and acceptability of medication abortion provision at a state university PI

**2018-20** What Will it Take? Expanding Medical Abortion Access with Family Physicians PI

Marji Gold, MD

Curriculum Vitae

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**2019-21** How does a chatbot fit into abortion care? Assessing common questions asked to the Carafem mobile platform and patient motivation for use PI

**2020-22** Quality Improvement Network for Contraceptive Access (QINCA) 2.0: NYC Health Care Facility Learning Collaborative co-PI

### **SPECIAL AWARDS**

1998 STFM Regional Meeting – first place award for seminar presentation “Helping Patients and Families with End-of-Life Decisions”

1998 DFMS Teaching Award

2000-03 Medicine as a Profession Fellowship, sponsored by Open Society Institute Project to integrate reproductive health services and training into family medicine residency programs in underserved urban communities

2003 STFM Innovative Teaching Award presented at national meeting, Atlanta, GA

2005 STFM Regional Meeting, Third Place award for seminar presentation “Designing and Implementing a Competency and Patient-Centered Curriculum in Women’s Health/Gynecology”, Vanita Kumar, MD, Marji Gold, MD

2006 Membership in Davidoff Society – For Excellence in Medical Student Teaching

2014 Faculty Mentoring Award – Society for Family Planning

### **PROFESSIONAL SOCIETY MEMBERSHIP**

American Academy of Family Physicians (AAFP)  
Society of Teachers of Family Medicine (STFM)  
Board Member – National Abortion Federation (NAF)

### **BOARD CERTIFICATION**

Diplomate, American Board of Family Medicine

### **AECOM/MONTEFIORE COMMUNITY SERVICE**

AECOM Division of Education – until 12/04

AECOM Committee on Appointments (Professor Level) 1998-2001

Marji Gold, MD Curriculum Vitae  
DFSM Division of Education – until 12/14

5

DFSM Leadership Group – until 12/14

DFSM Recruitment Committee/ad hoc faculty - current member

DFSM Committee Against Racism

DFSM Diversity & Inclusion Task Force

DFSM Committee on Appointments - Chair

## **PROFESSIONAL ORGANIZATION LEADERSHIP ACTIVITIES**

Society of Teachers of Family Medicine  
Member, Collaborative for Abortion Training and Access  
Member, Collaborative on Minority Health  
Member, Collaborative on Women's Health

2002-2010 -Society of Family Planning  
Member at-large, Board of Directors

2012-present Board Member – National Abortion Federation (NAF)

2012-present – Editorial Board of Contraception

## **OTHER PROFESSIONAL ACTIVITIES**

1992- Peer reviewer for Journal of Family Practice

1993- Peer reviewer for Family Medicine

1994 **Invited participant for National Cancer Institute** Symposium  
Review of multicultural materials for patient education

1994,1998 **Invited workshop participant for Wellstart International**  
"Integrating Lactation Management in Medical School and Residency Curricula"

1994-2001 Primary Investigator for Montefiore for the US collaborative ARM trial of q  
mifepristone/misoprostol in the US

2002- Peer reviewer for Families, Systems, and Health

2003- Peer reviewer for Annals of Family Medicine

2010- Peer reviewer for Contraception

Marji Gold, MD

Curriculum Vitae

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**SELECTED OUTSIDE PRESENTATIONS**

- 1987 STFM regional Meeting, Cambridge, Mass., October 11-13  
workshop "Working Women with Young Children"
- 1988 STFM National Meeting, Baltimore, Md., April 23-27  
workshop "Breastfeeding: Improving our Support Skills"  
workshop "Working Women with Young Children"
- 1989 STFM: Family in Family Medicine Meeting, Amelia Island, Fla.  
and National Meeting, Denver, Colo., April 30-May 3  
workshop "Non-Traditional Families: Dealing with Stereotypes"
- 1989 STFM Regional Meeting, Hershey, Pa., Oct. 11-13  
workshop "Learning to Listen to Ourselves: The Impact of Language"
- 1990 STFM: Family in Family Medicine Meeting, Amelia Island, Fla.  
and National Meeting, Seattle, Wash. May 5-9  
workshop "Learning to Listen to Ourselves: The Impact of Language"
- 1990 STFM Regional Meeting, New York, N.Y. Oct. 25-27  
workshop "Should Boys Play with Dolls?: A Family Physician looks at Sex-  
Role Stereotypes"
- 1991 STFM: Family in Family Medicine, Amelia Island, Fla.  
workshop "Should Boys Play with Dolls?: A Family Physician looks at Sex-  
Role Stereotypes"
- 1992 STFM Regional Meeting, Lancaster, Pa. Oct., 2-4  
"Collaboration with Midwives: Another Look at the Family Physician's Role  
in Maternity Care"
- 1994 STFM National Meeting, Atlanta, Ga., April 30-May 4  
and STFM Regional Meeting, Philadelphia, Pa., Oct. 28-30
- Invited presentation** "Choices Counseling: Helping Women Decide  
About Abortion"
- 1995 STFM Regional and National Meetings  
"Developing an Advisor-Advisee Relationship"
- 1997 STFM National Meeting, Boston, Mass.  
  
"Stories from long-term relationships with patients"
- 1998 STFM Regional Meeting, New Brunswick, New Jersey  
"Helping Patients and Families with End-of-Life Decisions"

Marji Gold, MD	Curriculum Vitae	7
1999	STFM Regional Meeting “New Choices in Early Pregnancy Interruption”	
2000	National Abortion Federation <b>Invited facilitator</b> “Incorporating teaching of early abortion techniques into residency education”	
2000	STFM National Meeting “New Choices in Early Pregnancy Interruption” Breakfast Table - “Supporting Breastfeeding - Overcoming Obstacles”	
2000	STFM Regional Meeting “The Visit Before the Morning After: Teaching about Emergency Contraception” “What’s the Point in PowerPoint?”	
2000	STFM/AAFP Conference on Patient Education 11/00 “Counseling patients for early pregnancy termination”	
2001	STFM Regional Meeting, Mystic, Conn. “Can the Umass Gnome Teach Abortions?” “Can We Really Do <i>That</i> in Family Medicine?” “Using Health Care Maintenance Forms for Teaching”	
2001	STFM/AAFP Patient Education Conference, Seattle, Wash. “Update on Integration of Medical Abortion into Family Medicine” “Talking to Patients about Emergency Contraception”	
2002	STFM Families and Health Conference, San Diego, Calif. (Seminar) STFM National Meeting, San Francisco, Calif. (Poster) “The Visit Before the Morning After: Teaching about Emergency Contraception”	
2002	STFM Regional Meeting, Cleveland, Ohio “Defining Competencies for Pregnancy Prevention”	
2002	APHA National Meeting, Philadelphia, PA “Barriers to Medical Abortion in Community Settings.”	
2002	<b>Invited speaker</b> “Update in Women’s Reproductive Health Care” Presented at Updates in Family Medicine, San Francisco, Calif.	
2003	National Abortion Federation, Seattle, Wash. <b>Invited Presentation</b> “Evaluation of “sono-as-needed” protocol for medical abortion in a community practice”	
2004	<b>Invited Grand Rounds Speaker</b> Beth Israel Medical Center, NY,NY	

Marji Gold, MD	Curriculum Vitae	8
	Breastfeeding Support in the Family Medicine practice, Joon Lee, MD, Marji Gold, MD	
2004	Annual National Abortion Federation Meeting, New Orleans, LA <b>Invited Presentation</b> "Sono as Needed: Implementing Medical Abortions at Community Health Centers" – Marji Gold, M.D., Ruth Lesnewski, M.D., Tanya Panton, M.D.  "3rd Annual Family Practice Roundtable: Abortion Care in a Family Medicine Setting" – Marji Gold, M.D., Linda Prine, M.D.	
2004	STFM Annual Conference, Toronto, Ontario, Canada, "Medical Abortion Cases" Roundtable – Nikki Colodny, Marji Gold, M.D., Susan Hadley, M.D., Vanita Kumar, M.D., Ruth Lesnewski, M.D., Linda Prine, M.D., M.D., Max Yarowsky, M.D.  "Teaching Residents Across the Abortion Divide" – Marji Gold, M.D., William Toffler, M.D., Daniel Vinson, M.D., MSPH	
2004	World Health Conference of Family Doctors (WONCA), Orlando, Florida, "Using the Manual Vacuum Aspiration Syringe for Incomplete and Spontaneous Abortion, Endometrial Biopsy and Early Pregnancy Termination in Primary Care Outpatient Settings" – Marji Gold, M.D., Linda Prine, M.D.	
2004	STFM Northeast Regional Meeting, Rye Brook, New York, "Centering Pregnancy: A New Approach to group Prenatal Visits" –David Walker MD , Evia Nano, MD, Marji Gold, MD  "The Visit Before the Morning After: Providing Advanced Prescription for Emergency Contraception" Vanita Kumar MD, Louisa Hann MD, Marji Gold, MD	
2004	STFM/AAFP Patient Education Conference, San Francisco, CA "Improving Access To Emergency Contraception- A Collaborative Approach To Patient Education And Systems Change" Louisa Hann MD, Marji Gold, MD	
2005	STFM Conference on Families and Health, Amelia Island, FL "The Reflective Practitioner Group: Integrative training for residents learning early abortion" – Marji Gold, M.D., Barbara Gawinski, PhD.	
2005-19	Annual National Abortion Federation, Montreal, Canada "4 <sup>rd</sup> Annual Family Practice Luncheon Roundtable: Abortion Care in a Family Medicine Setting" – Marji Gold, M.D., Linda Prine, M.D	
2005	STFM National Meeting, New Orleans, LA	



Marji Gold, MD

Curriculum Vitae

9

**Invited Facilitator** “Balancing Work and Life”, Women’s Theme Day Roundtable, Marji Gold, MD

“Improving Women’s Health: The Reproductive Health Initiative (RHI) Model Curriculum”, Marji Gold, MD, Jen Hurlburt

“Skills for Procedure Training: Faculty Development in Reproductive Health” – Marji Gold, M.D., Suzan Goodman, M.D., Linda Prine, M.D., Larry Leeman, M.D.

2005 NAPCRG Montreal Canada  
 “How Do You Train Family Medicine Residents to Be Abortion Providers?” (poster) Christine Dehlendorf, Dahlia Brahmi, David Engel, Kevin Grumbach, Carole Joffe, Marji Gold

2005 STFM Regional Meeting, Hershey, PA  
 “Designing and Implementing a Competency and Patient-Centered Curriculum in Women’s Health/Gynecology”, Vanita Kumar, MD, Marji Gold, MD

“Learning to Listen to Ourselves: Teaching Women-Centered Language in Reproductive Health”, Louisa Hann, MD, Vanita Kumar, MD, Marji Gold, MD

2005 **Invited Grand Rounds Speaker**  
 Group Health Cooperative Family Practice Residency, Seattle, WA  
 “Integration of Medication Abortion into a Primary Care Setting,” - Marji Gold, M.D

2005 **Invited Grand Rounds Speaker**  
 Swedish Family Medicine Residency Program, Providence Campus , Seattle, WA  
 “Integration of Medication Abortion into a Primary Setting,” Seattle, WA – Marji Gold, M.D

2005 **Invited Grand Rounds Speaker**  
 UCSF/SFGH Family & Community Medicine Residency Program, San Francisco, CA “Integration of Medication Abortion into a Primary Care Setting,” San Francisco, CA- Marji Gold, M.D

2005 **Invited Grand Rounds Speaker**  
 Dept. of Family Medicine, University at Buffalo “Integration of Medication Abortion into a Primary Care Setting,” Buffalo, NY- Marji Gold, M.D

2005 **Invited Grand Rounds Speaker**  
 Dept. of Family Medicine, University of Massachusetts, Worcester, MA, “Timely Initiation of Contraception – and What if it Isn’t?”

Marji Gold, MD

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2005

**Invited Grand Rounds Speaker**

UMDNJ Robert W. Johnson Family Medicine Residency Program, New Brunswick, NJ “Integration of Medication Abortion into a Primary Care Setting,” - Marji Gold, M.D, Justine Wu, MD

2006

National Abortion Federation Annual Meeting San Francisco, CA  
Research presentation “How Do You Train Family Medicine Residents to Be Abortion Providers?” Christine Dehlendorf MD, Dahlia Brahmi MD, Marji Gold MD

Breakfast session – “Training Issues in Abortion Care”  
Marji Gold MD and Eve Espey MD

“5th Annual Family Practice Luncheon Roundtable: Update on Abortion Training in Family Medicine”, Linda Prine MD, Vanita Kumar MD, Marji Gold MD

Research Poster - “Reproductive Health Beliefs of Indo-Caribbeans”  
Kamini Geer MD, Marji Gold, MD

Research Poster – “Integration of early abortion services into primary care: an acceptability survey of female patients”, Susan Rubin, MD, Marji Gold, MD

2006

STFM National Meeting, San Francisco, CA

**Invited Presentation** Preconference – Celebrating Women in Family Medicine

“The Feminization of Medicine: A SWOT Analysis”, Marji Gold, MD

Breakfast Table – “Narratives of Choice: Pregnancy Options Decision Making” Cori Blum MD, Marji Gold MD

Workshop: “Writing a proposal for funding to integrate abortion and family planning into your residency curriculum” Marji Gold MD

Research Poster - “Reproductive Health Beliefs of Indo-Caribbeans”  
Kamini Geer MD , Marji Gold MD

Research Poster - “Integration of early abortion services into primary care: an acceptability survey of female patients” Susan Rubin MD, Emily Godfrey, MD, Marji Gold, MD

2006

**Invited Grand Rounds** Columbia-Presbyterian Family Medicine Residency Program, NY, NY

“Taking Phone Calls from Medication Abortion Patients”, Marji Gold, MD, Yael Swica, MD

Marji Gold, MD	Curriculum Vitae	11
2006	<b>Invited Speaker</b> UCSF/SFGH Family & Community Medicine Residency Program/Primary Care Internal Medicine "The Politicization of Reproductive Health" Marji Gold MD, Carole Joffe Christine Dehlendorf, MD	
2006	<b>Invited Grand Rounds Speaker</b> OHSU (Portland, Oregon) Department of Family Medicine "Medication Abortion in Family Medicine" Teresa Gipson MD, Marji Gold MD	
2006	<b>Invited Workshop Presentation</b> Family Medicine Residency of Idaho, Boise, Idaho "MVA for Miscarriage Management/Using Papayas to Teach Hands-On Skills" Marji Gold MD	
2006	STFM Regional Meeting Boston (Danvers) MA "Cinema and the Speculum: Using Popular Film Clips to Teach Patient-Centered Language and Behavior During Pelvic Exams" Sayantani DasGupta, MD, Marji Gold, MD  "Contraceptive Risk, It's all Relative: Helping Patients Understand Risk and Contraceptive Choices", Vanita Kumar, MD, Marji Gold, MD  Research Presentation "Integration of early abortion services into primary care: an acceptability survey of female patients" Susan Rubin, MD, Marji Gold MD  "Timely Initiation of Contraception" Emily Jackson, MD, Adjoa Duker, MD, Marji Gold, MD	
2006	<b>Invited Grand Rounds Speaker</b> Dept. of Family Medicine, Lehigh Valley Medical Center, Allentown, PA "Timely Initiation of Contraception – and What if it Isn't?"	
2006	AAFP/STFM Conference on Patient Education/Quality Improvement, Denver, CO. "Cervical cancer screening and contraception across the lifecycle", Joquetta Paige, MD, Marji Gold, MD  "Learning to Listen to Ourselves: Using Patient-Centered Language to Improve Reproductive Health Care" Joquetta Paige, MD, Marji Gold, MD	
2006	<b>Invited Keynote Speaker</b> Medical Students for Choice Regional Conference Bronx, NY  "Integrating Abortion Care into Routine Office Practice – or Where Will You Work as a Pro-Choice Doctor" Marji Gold, MD	
2007	National Abortion Federation Annual Meeting, Boston, MA 4/07	

Marji Gold, MD

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“Cross-Discipline Collaboration for Abortion Training”, Marji Gold, MD, Larry Leeman, MD, Eve Espey, MD

2007 Society of Teachers of Family Medicine, National Meeting, Chicago, IL 5/07

“Learning to Listen to Ourselves: Teaching Patient-centered Language in Reproductive Health” Marji Gold, MD; Vanita Kumar, MD; Justine Wu, MD

“Teaching Women's Reproductive Health Care”, Linda Prine, MD; Marji Gold, MD; Suzan Goodman, MD, MPH; Monique Thiry-Zaragoza, MD; Debra Stulberg, MD; Christine Delendorf, MD; Susan Rubin, MD; Susan Hadley,, MD; Vanita Kumar, MD; Peter Sawires, MA; Kristin Moore , MPA

“Cinema and the Speculum: Using Popular Film Clips to Teach Patient-centered Language and Behavior”, Marji Gold, MD, Emily Jackson MD

“Skills for Procedure Training—Faculty Development in IUD Insertion”, Linda Prine, MD; Julie Sicilia-May, MD; Ginger Gillespie, MD; Vanita Kumar, MD; Marji Gold, MD

2007 Association of Reproductive Health Professionals National Meeting Minneapolis, MN 9/07

“Availability of Emergency Contraception From US College Student Health Centers” (research poster), Kathleen Devine MD, Evelyn Hessing MD, Marji Gold MD

2007 Society of Teachers of Family Medicine, Northeast Regional Meeting, Pittsburgh, PA 10/07

**Third Prize for Outstanding Presentation** “Language matters: woman-centered talk as a fundamental skill during pelvic exams”, Marji Gold, MD, Lucy Candib, MD, Sara Shields, MD

“Addressing Contraceptive Needs of Adolescent Females by Providing More Effective Teen Friendly Family Planning Services “, Adjoa Duker MD, Marji Gold MD

Does Cervical Cancer Screening Impede Access To Contraceptives? An Assessment Of Knowledge And Behaviors Among Family Physicians (poster)  
Joquetta Paige MD, Marji Gold MD

Universal Voluntary Screening Of Adolescents In A School-Based Clinic

Marji Gold, MD	Curriculum Vitae	13
	For Gonorrhea And Chlamydia (poster) Margaret Rosenberg MD, Marji Gold MD, Mayris Webber PhD, David Appel MD	
2007	National Primary Care Research Group National Meeting, Vancouver BC, 10/07  Changing the Face of Reproductive Health: Discussions of Pregnancy and Contraception With Men (poster) Emily Jackson, MD; Marji Gold  Early Abortion Services Within Primary Care: Factors Predicting Acceptability From Patients at Two Abortion Clinics (poster) Emily Godfrey, MD, MPH; Susan Rubin; Erica Smith; Marji Gold  Integration of Early Abortion Services Into the Family Medicine Clinic: Acceptability Survey of Female Patients (presentation) Susan Rubin, MD, MPH; Emily Godfrey; Marji Gold  Acceptance of Early Abortion Services in Primary Care Settings: A Comparison of Abortion Clinic and Family Medicine Patients in Chicago (presentation) Erica Smith; Emily Godfrey; Susan Rubin; Marji Gold	
2007	<b>Invited Speaker</b> Doctors for a Women's Choice for Abortion – Celebration of 40 years of Legal abortion in the United Kingdom, London, UK 10/07 “Training the next generation of abortion providers in the United States”, Marji Gold, MD	
2008	Society of Teachers of Family Medicine Annual Meeting, Baltimore, MD, 4/30-5/4  Women in Family Medicine (pre-conference workshop) Marji Gold MD  Reproductive Health and Sexual Health Needs of Men Emily Jackson MD, Marji Gold MD  Addressing the Health Issues of Lesbians and WSW (Women who Have Sex with Women) Tara Stein MD, Silvia Amesty MD, Emily Jackson MD, Marji Gold MD  Family Medicine Patient Preferences in Early Abortion: A Survey of Chicago and New York Patients Emily Godfrey MD MPH, Susan Rubin MD, Erica Smith BA, Marji Gold MD  IUDS: What You Need to Know	

Marji Gold, MD	Curriculum Vitae	14
	Marissa Harris MD, Emily Jackson MD, Marji Gold MD	
2008	Society of Teachers of Family Medicine North East Regional Conference, Baltimore, MD	
	Teaching systems-based practice: building upon residents' experiences with training in multiple settings Cara Herbitter MPH, Marji Gold MD	
	Improving Our Approach to Screening for STIs in Adolescents Meg Rosenberg MD, Marji Gold MD	
	Why Good Docs Make Bad Presentations and How You Can Avoid Their Fate Marissa Harris MD, Tara Stein MD, Marji Gold MD	
	Contraception In Adolescents: An Update On Improving Continuation Adjoa Duker MD, Marji Gold MD	
	<b>First Prize for Best Seminar:</b> Language Matters: Woman-Centered Talk during Pelvic Exams" – Sara Shields MD, Lucy Candib MD, Marji Gold MD (First Prize for Best Seminar at the Meeting)	
	A Discussion about PAP Testing Before IUD Insertion in the Absence of Clear Guidelines Tara Stein MD, Marji Gold MD	
	NYC Women's Health Free Clinic: A Model for Expanding Reproductive Health Services and Training Honor MacNaughton MD, Elizabeth McCormick MD, Natasha Kelly DO, Vanessa Batista MSIV	
	What is the Extent of Family Planning Training in Family Medicine Programs? Cara Herbitter MPH, Marji Gold MD, Megan Greenberg	
	Incorporation of Reproductive Attitudes and Beliefs of Specific Cultural Groups in Delivery of Family Planning Services Marissa Harris MD, Marji Gold MD	
2008	North American Primary Care Research Group, Rio Grande, Puerto Rico	
	Abortion Training at Multiple Sites: An Unexpected Curriculum for Teaching Systems-Based Practice Cara Herbitter MPH, Vanita Kumar MD, Alison Karasz MD, Marji Gold MD	
	What is the Extent of Family Planning Training in Family Medicine Programs?	

Marji Gold, MD

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Jessica Dalby MD, Crystal Query, Cara Herbitter MD, Megan Greenberg, Marji Gold

Reproductive Attitudes of a Convenience Sample of Reproductive Ages West-Indian Women Residing in New York City  
Marissa Harris MD, Marji Gold MD

Providers' Attitudes about PAP Smears, Colposcopy, and the Intrauterine Device  
Tara Stein MD, Marji Gold MD

Men's Attitudes Toward Contraception, Pregnancy and Abortion: A Qualitative Study  
Emily Jackson MD, Marissa Harris MD, Marji Gold MD

2009 National Abortion Federation Annual Meeting, Portland, OR

BA

Improving Reproductive Health Education for Family Medicine Residents  
Crystal Query MD, Marji Gold MD, Cara Herbitter MPH, Megan Greenberg

2009 Society of Teachers of Family Medicine Annual Meeting, Denver, CO

Strategies for Teaching Residents Pregnancy Options Counseling  
Cara Herbitter MPH, Vanita Kumar MD, Alison Karasz PhD, Marji Gold MD

Is Pap Screening a Barrier to IUD Insertion: a Review of the Current Guidelines  
Tara Stein MD, Marji Gold MD

Improving Reproductive Health Education for Family Medicine Residents  
Marji Gold MD, Cara Herbitter MPH, Megan Greenberg BA

2009 Association of Reproductive Health Professionals National Meeting, Los Angeles, CA

US Family Physicians' Knowledge, Attitude and Practice with Intrauterine Contraception  
Susan Rubin MD, Marji Gold MD

What is the Extent of Family Planning Training in Family Medicine Residencies?  
Marji Gold MD, Cara Herbitter MPH, Megan Greenberg BA

2009 The Society of Teachers of Family Medicine North East Regional Conference, Rye Brook, NY

Strategies to Increase IUD Training in Family Medicine Residencies



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Marji Gold MD, Linda Prine MD, Megan Greenberg BA

Perceived Barriers to Contraception in an Underserved Population  
Sharon Bennatabou MD, Marji Gold MD

RHP: Outcomes of a Unique Abortion Training Program  
Megan Greenberg BA, Cara Herbitter MPH, Barbara Gawinski PhD, Marji Gold MD

Barriers to Access to Reproductive Health Care in Family Medicine  
Marji Gold MD

2009 North American Primary Care Research Group, Montreal, Quebec

Reproductive Health Program: Outcomes of a Unique Abortion Training  
Megan Greenberg BA, Jason Fletcher PhD, Cara Herbitter MPH, Marji Gold MD

2010 National Abortion Federation Annual Meeting, Philadelphia, PA

Passing the Torch – Educating Medical Students & Training Residents  
Larry Leeman MD, Eve Espey MD, Marji Gold MD

2010 Society of Teachers of Family Medicine Annual Meeting, Vancouver, BC

Conversations About Abortion Self-induction: Promoting Women-centered  
Care and Policy

Marji Gold, MD; Christine Dehlendorf, MD; Dan Grossman, MD; Melanie Pena, MPH; Kelly Blanchard, MPH

The Reproductive Health Program at the University of Rochester: What  
Can We Learn From Trainees?

Barbara Gawinski, PhD; Megan Greenberg, BA; Cara Herbitter, MPH;  
Marji Gold, MD; Jason Fletcher, MA, MS, PhD

Medical Students as Patients: An Experiential Learning Project About  
Emergency Contraception and Patient-centered Care

Cara Herbitter, MPH; Jason Fletcher, PhD; Alice Fornari, EdD, RD; Leslie Boden, MSUP; Marji Gold, MD

Addressing the Health Needs of Transgender Patients

Cara Herbitter, MPH; Nicole Kirchen, MD, MPH; Tara Stein, MD; Marji Gold, MD

Strategies to Increase IUD Training in Family Medicine Residencies

Marji Gold, MD; Megan Greenberg, BA; Cara Herbitter, MPH; Linda Prine, MD; Jason Fletcher, PhD



Marji Gold, MD	Curriculum Vitae	17
	Uncertainty In Clinical Decision Making: Embracing the Challenges for Educators and Learners Ellen Tattelman, MD; Marji Gold, MD; Margaret Rosenberg, MD	
	Reproductive Attitudes and Health Beliefs of West-Indian Women In New York City Marissa Harris MD, MPH, Cara Herbitter MPH, Marji Gold MD	
	Language Matters: Woman-centered Talk During Pelvic Exams Sara Shields, MD, MS; Lucy Candib, MD; Marji Gold, MD	
	Perceived Barriers to Reproductive Health Care in a Homeless Population Arati Karnik, MD; Sharon Phillips, MD; Andrea Littleton, MD; Marji Gold, MD	
2010 Atlanta GA	Association of Reproductive Health Professionals National Meeting,  The Reproductive Health Program: Outcomes of a Unique Abortion Training Program (poster) Megan Greenberg, Cara Herbitter MPH, Barbara Gawinski PhD, Jason Fletcher PhD, Marji Gold MD	
2010	Family Medicine Education Consortium North East Regional Conference, Hershey PA  Preventing Unwanted Teen Pregnancy: The Importance of offering IUDs in a School Health Setting (Breakfast Discussion) Tara Stein MD, MPH, Marji Gold MD  Women's Abortion Experiences in Family Medicine: A Multi-Site, Cross-Sectional Survey Justine Wu MD, MPH, Emily Godfrey MD, MPH, Linda Prine MD, Honor MacNaughton MD, Marji Gold MD  Medication Abortion: Frequently Asked Questions / Simplifying Medical Abortion: Home-Use of Mifepristone Kohar Der Simonian MD, Lindsay Faucette MD, Victor Sta. Ana MD, Honor MacNaughton MD / Marji Gold MD, Linda Prine MD, Sarah Miller MD, Sharon Phillips MD  Students as Patients and Teachers: An Evaluation of an Experiential Emergency Contraception Project (Poster) Cara Herbitter MPH, Jason Fletcher PhD, Leslie Boden MSUP, Alice Fornari EdD, RD, Marji Gold MD	
2010 WA	North American Primary Care Research Group Annual Meeting, Seattle,	

Marji Gold, MD

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Ambivalence About Pregnancy Planning: A Qualitative Study of Providers And The Women They Counsel  
Sarah Miller, MD, Marji Gold, MD; Shama Samant, BS; Alison Kliegman, BA

The Reproductive Experiences of Homeless Women: A Mixed-Methods Study  
Sharon Phillips, MD, Marji Gold, MD

Students As Patients And Teachers: An Evaluation of an Experiential Emergency Contraception Project  
Cara Herbitter, MPH, Jason Fletcher, PhD; Alice Fornari, EdD, RD; Leslie Boden, MSUP; Marji Gold, MD

Evaluating Primary Care Access In Different Healthcare Systems: Comparison, Collaboration, And Research Capacity Building  
Sarah Lesko, MD, MPH, Jennifer Devoe, MD, DPhil; Shabnam Asghari, MD, MPH, PhD; Barry Saver, MD, MPH; Catherine Drouin, PhD; George Freeman, MD; Marji Gold, MD; Emily Marshall, MD; Trudy Singzon, MD, MPH; Marshall Godwin, MD, Msc, FCFP

2011

Society of Teachers of Family Medicine Annual Meeting, New Orleans, LA

An Evaluation of an IUD Initiative at Family Medicine Residency Programs (poster)  
Cara Herbitter, MPH; Jason Fletcher, PhD; Finn Schubert, BA; Megan Greenberg, BA; Marji Gold, MD

Integrating Abortion Training Into Family Medicine Residencies: Critical Factors and Useful Practices  
Marji Gold, MD; Finn Schubert, BA; Cara Herbitter, MPH

Changing Conversations About Abortion in Family Medicine  
Cara Herbitter, MPH; Marji Gold, MD; Finn Schubert, BA; Sarah Stumbar, MPH

Uterine Aspiration and Intrauterine Device Placement Using a Papaya Model and Patient-Centered Communication  
Sarah Miller, MD; Sharon Phillips, MD; Leah Rothman, DO; Rachel Roth, DO; Marji Gold, MD; Linda Prine, MD; Dana Schonberg, MD

Women's Abortion Experiences in Family Medicine: A Multi-site, Cross-sectional Survey  
Justine Wu, MD, MPH; Emily Godfrey, MD, MPH; Honor McNaughton, MD; Linda Prine, MD; Kathryn Anderson-Clark, PhD; Marji Gold, MD

Uncertainty in Clinical Decision Making: Embracing the Challenges for Educators and Learners  
Ellen Tattelman, MD; Margaret Rosenberg, MD; Marji Gold, MD

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Perspectives On Reproductive Healthcare Access Among Homeless Girls Living In Family Shelters In The Bronx  
Lin-Fan Wang; April Wilson; Sharon Phillips; Andrea Littleton; Marji Gold

2011 Family Medicine Education Consortium North East Regional Conference, Danvers, MA

Countering Misinformation from Crisis Pregnancy Centers: Issues for Resident and Patient Education (poster)  
Marji Gold MD, Dana Schonberg MD, Lin-Fan Wang MD, Finn Schubert BA,  
Cara Herbitter MPH

An Evaluation of an IUD Initiative at Family Medicine Residency Programs  
Cara Herbitter MPH, CPH, Jason Fletcher PhD, Finn Schubert BA, Megan Greenberg RN, Marji Gold MD

Patient-Centered Papaya Workshop  
Sarah B. Miller MD, MPH, Lucia McLendon MD, Ginger Gillespie MD, Marji Gold MD, Linda Prine MD, Julie A. Johnston MD, Catherine Romanos MD, Marjorie Affell MD, MPH

Taking the Training Wheels Off: Abortion Training as a Paradigm for Involving Trainees in Procedural Care  
Sarah Miller MD, MPH, Zowie Barnes MD, Honor MacNaughton MD, Tara Stein MD, MPH, Sharon Phillips MD, MPH, Marji Gold MD

2011 North American Primary Care Research Group Annual Meeting – Banff, Canada, Nov. 2011

Pregnancy Ambivalence: A Qualitative Study of Providers and the Women They Counsel (poster)  
Sarah Miller MD MPH, Ariana Bennett, MPH

Contraceptive Needs of Women Incarcerated at Rikers Island Jail Complex (poster)  
Dana Schonberg MD, Marji Gold MD, Ariana Bennett, MPH

Women's Abortion Experiences in Family Medicine: A Multi-site, Cross-sectional Survey (poster)  
Justine Wu MD MPH, Emily Godfrey MD MPH, Honor MacNaughton MD, Linda Prine MD, Kathryn Andersen-Clark PhD, Marji Gold MD

Acceptability of Home Use of Mifepristone for Medical Abortion (poster)  
Marji Gold MD, Finn Schubert, Cara Herbitter MPH, Yael Swica MD MA, Erica Chong MPH

Marji Gold, MD	Curriculum Vitae	20
	An Evaluation of an IUD Initiative at Family Medicine Residency Programs Cara Herbitter MPH, Jason Fletcher PhD, Finn Schubert, Megan Greenberg RN, Ariana Bennett MPH, Marji Gold MD	
2012	National Abortion Federation Annual Meeting – Vancouver, Canada, April 2012	
	Contraceptive Needs of Women Incarcerated at Rikers Island Jail Complex (poster) Dana Schonberg MD, Marji Gold MD, Ariana Bennett MPH	
	A Review of Abortion, Family Planning, and Miscarriage Management Content in Family Medicine Textbooks (poster) Sarp Aksel, Marji Gold MD, Finn Schubert, Ariana Bennett MPH, Cara Herbitter MPH	
	Training the Next Generation of Providers Larry Leeman MD, Marji Gold, MD	
	11th Annual Family Medicine Luncheon Marji Gold MD, Linda Prine, MD	
2012	STFM Annual Spring Meeting – Seattle, WA, April 2012	
	Countering Misinformation From Crisis Pregnancy Centers: Issues for Resident and Patient Education Marji Gold MD, Dana Schonberg MD, Lin-Fan Wang MD, Finn Schubert, Cara Herbitter MPH	
	Working Part Time in Academic Family Medicine: A Panel Discussion Sarina Schrager MD MS, University of Wisconsin; Tracy Juliao PhD, St John Hospital Family Practice, Farmington Hills, MI; Marji Gold MD, Albert Einstein College of Medicine; Mari Egan MD MHPE, University of Chicago; Cheryl Seymour MD, Maine Dartmouth Family Medicine Residency, Augusta, ME	
	Representations of Abortion in Pop Culture: Helping Learners Develop Media Awareness and Teaching Skills Marji Gold MD, Dana Schonberg MD, Lin-Fan Wang MD, Cara Herbitter MPH, Finn Schubert, Ariana Bennett MPH	
	Mystery in Medicine: Comfort With the Unknown Ellen Tattelman MD, Margaret Rosenberg MD, Marji Gold MD	
	Contraceptive Needs of Women Incarcerated at Rikers Island Jail Complex Dana Schonberg MD, Ariana Bennett MPH, Marji Gold MD	

Marji Gold, MD	Curriculum Vitae	21
	Ambivalence About Pregnancy Planning: A Qualitative Study of Providers and the Women They Counsel	
	Sarah Miller MD, Ariana Bennett MPH, Marji Gold MD	
	Advocacy for Reproductive Health: Successes and Challenges	
	Sharon Phillips, MD MPH; Dana Schonberg MD, Lin-Fan Wang MD, Marji Gold MD	
2012	Family Medicine Education Consortium Northeast Regional Meeting 2012 – Cleveland, OH, September 2012	
	Physicians as Advocates for Reproductive Health	
	Lin-Fan Wang MD, Dana Schonberg MD, Jennifer Amico MD, Marji Gold MD	
	Pregnancy Options Counseling Training as a Paradigm for Teaching Trainees about Counseling Patients	
	Dana Schonberg MD, Lin-Fan Wang MD, Tara Stein MD, Marji Gold MD	
	A Review of Abortion, Family Planning, and Miscarriage Management Content in Family Medicine Textbooks (poster)	
	Sarp Aksel, Marji Gold MD, Finn Schubert, Ariana Bennett MPH, Cara Herbitter MPH	
	Addressing the Health Needs of Transgender Patients	
	Cara Herbitter MPH, Finn Schubert, Ariana Bennett MPH, Marji Gold MD	
	Representations of Abortion in Pop Culture: Helping Learners Develop Media Awareness and Teaching Skills	
	Marji Gold MD, Dana Schonberg MD, Lin-Fan Wang MD, Cara Herbitter MPH, Finn Schubert, Ariana Bennett MPH	
	Menopause and Beyond: Women’s Sexual Health and Experiences	
	Alice S. Teich MD, Lin-Fan Wang MD, Marji Gold MD	
2013	National Abortion Federation Annual Meeting – April 2013	
	Pre-Conference: Training the Next Generation: Integration of Abortion into Clinician Education	
	Marji Gold MD	
2013	STFM Annual Spring Meeting – Baltimore, MD, April 2013	
	Management of EPF and Abortion by FM Educators (poster)	
	Cara Herbitter MPH, Ariana Bennett MPH, Finn Schubert BA, Iana Bennett MD PhD, Marji Gold MD	
	Eliciting Patient Understandings about Treatment Risk: Birth Control as Paradigm	

Marji Gold, MD

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Alice Teich MD, Dana Schonberg MD, Carol Mendez, Finn Schubert MD,  
Marji Gold MD

Perspective of Cambodian and Chinese Female Adolescents and Mothers  
about Sexual and Reproductive Health

Lin-Fan Wang MD, Ariana Bennett MPH, Marji Gold MD

Simplifying Medical Abortion

Marji Gold MD, Ariana Bennett MPH, Dana Schonberg MD, Lin-Fan Wang  
MD, Tara Stein MD

Sexual and Reproductive Health Professionalism Seminar

Carol Mendez MD, Marji Gold MD, Cara Herbitter MPH, Sarah Miller MD

Reproductive Health Legislative Updates

Lin-Fan Wang MD, Marji Gold MD, Jennifer Amico MD

2013

Family Medicine Education Consortium Northeast Regional Meeting  
2013– Philadelphia, PA, November 2013

Eliciting Patient Understandings about Treatment Risk: Birth Control as  
Paradigm

Jennifer Amico MD, Bhavik Kumar MD, Ariana Bennett MD, Marji Gold  
MD

Enhancing Postpartum Contraception

Bhavik Kumar MD, Jennifer Amico MD, Marji Gold MD

Management of Early Pregnancy Failure and Induced Abortion by Family  
Medicine Educators (poster)

Ariana Bennett MPH, Cara Herbitter MPH CPH, Finn Schubert BA, Ian  
Bennett MD PhD, Marji Gold MD

Professionalism in Matters of Sexual Health

Ariana Bennett MPH, Cara Herbitter MPH CPH, Finn Schubert BA, Ian  
Bennett MD PhD, Marji Gold MD

Representations of Reproductive Health Topics in Popular Magazines:  
Helping Learners Develop Media Awareness and teaching Skills (poster)

Ariana Bennett MPH, Finn Schubert BA, Steph Herold MPH, Courtney  
Taylor, Marji Gold MD

Professional Disagreement

Dana Schonberg MD MPH, Jennifer Amico MD, Bhavik Kumar MD, Marji  
Gold MD

Increasing Teen Access to IUDs by Expanding Our Network of training

Tara Stein MD MPH, Ariana Bennett MPH, Marji Gold MD

Marji Gold, MD	Curriculum Vitae	23
	Full Access to Reproductive Healthcare under the ACA: Educating Learners to Eliminate Barriers to Care Finn Schubert BA, Aleza Summit MPH, Bhavik Kumar MD, Ariana Bennett MPH, Marji Gold MD	
2013	Medical Students for Choice Annual Conference on Family Planning- Denver, CO November 2013	
	Social Contexts of Women's Decisions about Abortion Methods Finn Schubert BA, Marji Gold MD	
2013	North American Primary Care Research Group-Ottawa, Ontario, CA November 2013	
	How Patients Choose and Experience Early Abortion Care in the Family Medicine Setting (Poster) Aleza Summit MPH, Ariana Bennett MPH, Cara Herbitter MPH CPH, Alison Karasz PhD, Marji Gold MD	
	Under-Recognized Factors in Pregnancy in a Primary Care Population: Reproductive Coercion, Transactional Sex, Violence, and Ambivalence (Poster) Sharon Phillips MD MPH, Ariana Benntt MPH, Laura Krinsky, Marji Gold	
	Physicians' and Patients' Experiences with Early Elective IUD Removals (Poster) Jennifer Amico MD, Ariana Bennett MPH, Alison Karasz PhD, Marji Gold MD	
	A Study of Teen Access to and Acceptability of Intrauterine Devices (IUDs) (Poster) Tara Stein MD MPH, Ariana Bennett MPH, Steph Herold MPH, Marji Gold MD	
2014	National Abortion Federation Annual Meeting- San Francisco, CA April, 2014	
	Providing Abortion in Family Medicine as an Approach to Reduce Stigma and Anti-abortion Harassment Linda Prine MD, Marji Gold MD	
2014	Society of Teachers of Family Medicine Annual Spring Conference- San Antonio, TX May 2014	
	Best Practices for Educating Residents About Transgender Health Topics (Poster) Finn Schubert BA, Zil Goldstein MD, Marji Gold MD, Ariana Bennett MPH	
	The Future of Family Planning in Texas: Are Family Physicians Ready?	



Marji Gold, MD

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(Poster)

Bhavik Kumar MD, Arthur E. Blank MD, Marji Gold MD

Representations of Reproductive Health Topics in Popular Magazines:  
Helping Learners Develop Media Awareness/Teaching Skills (Poster)

Ariana Bennett MPH, Finn Schubert BA, Steph Herold MPH, Courtney  
Taylor, Marji Gold

Patient and Physician Experiences with Early Elective IUD Removals

Jennifer Amico MD, Ariana Bennett MPH, Marji Gold MD

Training Family Medicine Residents in a School-Based Health Center to  
Provide IUDs On-Site to Teens

Tara Stein MD MPH, Marji Gold MD, Ariana Bennett MPH

Addressing Stigmatized Health Care in Family Medicine Education

Ariana Bennett MPH, Finn Schubert BA, Aleza Summit MPH, Ellen  
Tattelman MD, Linda Prine MD, Marji Gold MD

eLearning for Pregnancy Loss: New Strategies to Teach Miscarriage  
Management in Family Medicine Settings

Robin Wallace MD, Grace Shih MD, Marji Gold MD

Understanding the Impact of Incarceration on Our Patients and Families

Dana Schonberg MD MPH, Lauren Casey BA, Ariana Bennett MPH, Marji  
Gold MD

Values Clarification Around Patients' Sexual Decision-Making

Evelyn Figueroa MD, Finn Schubert BA, Ariana Bennett, Aleza Summit,  
Marji Gold MD

Breaking Down Barriers: Exploring Health Disparities in Contraception  
Care

Georgie Broomfield MD, Venis Wilder MD, Bhavik Kumar MD, Linda Prine  
MD, Marji Gold MD

Gynecological Teaching Associates as a Model for Teaching Patient-  
Centered Women's Health Care

Marji Gold MD, Jennifer Amico MD, Aleza Summit MPH

2014

Family Medicine Education Consortium- Arlington, VA October 2014

Addressing Stigmatized Health Care in Family Medicine

Hilary Rosenstein MD, Ariana Bennett MPH, Ellen Tattelman MD, Marji  
Gold MD

Miscarriage Management Workshop

Sara Baird MD, Lily Pike MD, Linda Prine MD, Honor MacNaughton MD

Understanding Early Aspiration Abortion in the Family Medicine Setting



Marji Gold, MD

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Bhavik Kumar MD, Ariana Bennett MPH

Promoting Breastfeeding for Women/Babies Seen in Urban Community Health Centers

Joyce Roberts MD, Marji Gold MD, Aimee Mankodi MD, Laura Tavarez

Breaking down Barriers: Exploring Health Disparities in Contraception Care

Bhavik Kumar MD, Venis Wilder MD, Georgie Bromfield MD, Linda Prine MD, Marji Gold MD

Gynecological Teaching Associates as a Model for Teaching Patient-Centered Women's Health Care

Aleza Summit MPH, Tara Stein MD, MPH

Point of Care Screening for Abdominal Aortic Aneurysm

Linda Prine MD, Brian Ross MD, Chandra Singh MD

Values Clarification around Patients' Sexual Health Decision-Making

Finn Schubert BA, Evelyn Figueroa MD, Aleza Summit MPH, Ariana Bennett MPH, Marji Gold MD

Addressing Reproductive Needs through a Patient-Centered Lens:

Looking Beyond the Unintended/Intended Dichotomy

Sarah Miller MD, MPH, Aleza Summit MPH, Ariana Bennett MPH, Marji Gold MD

LARC Provision in Family Medicine: From Enhanced Residency Training to Post-Residency Practice (Poster)

Finn Schubert BA, Tara Stein MD, MPH, Marji Gold MD

Understanding the Impact of Incarceration on Our Patients and Families

Dana Schonberg MD, MPH, Lauren Casey BA, Ariana Bennett MPH

2014

North American Primary Care Research Group- New York, NY November 2014

LARC Provision in Family Medicine: From Enhanced Residency Training to Post-Residency Practice

Practice

Finn Schubert BA, Tara Stein MD, MPH, Marji Gold MD

Women's and Providers' Experiences with Early Elective IUD Removal

Jennifer Amico, MD, Ariana Bennett, MPH; Alison Karasz, PhD, Marji Gold MD

Contraception in Jail: What Do Women Want? A Qualitative Study

Marji Gold, MD	Curriculum Vitae	26
	Dana Schonberg, MD, MPH, Ariana Bennett, MPH, Alison Karasz, PhD, Marji Gold, MD	
2014	Medical Students for Choice Annual Conference- Atlanta, GA November 2014	
	Non-judgmental Contraceptive Counseling at the Time of an Abortion Marji Gold MD, Lauren Casey BA	
2015	Society of Teachers of Family Medicine- Orlando, FL April 2015	
	Developing Patient-Centered Teams: The Role of Sharing Stories About Patients and Patient Care Ariana Bennett MPH, Marji Gold MD	
	Enhanced Reproductive Health Training for Family Medicine Residents Aleza Summit MPH, Finn Schubert, Marji Gold MD	
	Breastfeeding Promotion in Urban Communities Aimee Mankodi MD, Marji Gold MD, Joyce Robert, Laura Tavaréz	
	Strategies to Improve Clinical and Didactic Education about IUDs and Contraceptive Implants in Family Medicine Residencies Finn Schubert, Tara Stein MD, Erica Bishop, Marji Gold MD	
	Looking Beyond the “Intended” Versus “unintended” Pregnancy: Addressing Reproductive Needs Through a Patient-Centered Lens Sarah Miller MD MPH, Aleza Summit MPH, Carolyn Pierce MD, Ariana Bennett MPH, Marji Gold MD	
	What Patients Value about Early Abortion Care in the Family Medicine Setting: Key Implications for Family Medicine Learners Aleza Summit MPH, Lauren Casey, Alison Karasz PhD, Marji Gold MD	
2015	National Abortion Federation- Baltimore, MD April 2015	
	Using Family Doctors to Increase the Abortion Provider Workforce in the Context of Stigma Linda Prine MD, Marji Gold MD	
2015	Family Medicine Education Consortium- Danvers, MA October 2015	
	Using Patient-Centered Language During Genitourinary (GU) Exams	

Marji Gold, MD

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Bhavik Kumar MD MPH, Alison Paul MD, Sara Sheilds MD, Navid Roder MD, Marji Gold MD

What Patients Value about Early Abortion Care in the Family Medicine Setting: Key Implications for Family Medicine Learners (Poster)

Aleza Summit MPH, Lauren Casey, Ariana Bennett MPH, Alison Karasz PhD, Marji Gold MD

Addressing the Needs of Patients Who Have Visited Crisis Pregnancy Centers

Lauren Casey, Marji Gold MD

Enhanced Reproductive Health Training for Family Medicine Residents

Aleza Summit MPH, Finn Schubert, Marji Gold MD

Pregnancy and Obesity: Offering respectful Reproductive Health Care to All Women in the Face of Stigma

Aleza Summit MPH, Hilary Rosenstein MD, Marji Gold MD

Providing Patient-Centered Contraceptive Counseling in the Context of Abortion Care

Hannah Helmy PhD MPH, Alison Paul MD, Marji Gold MD

Conversations about Reproductive Coercion in Family Medicine Education

Hilary Rosenstein MD, Sharon Phillips MD MPH, Ariana Bennett MPH, Marji Gold MD

Developing Patient-Centered Team: The Role of Sharing Stories about Patients and Patient Care

Ariana Bennett MPH, Marji Gold MD

2015

North American Primary Care Research Group- Cancun Mexico October 2015

Access to the Copper IUD as Emergency Contraception in Nine U.S. Cities

Finn Schubert, MPH; Erica Bishop; Marji Gold, MD

The Future of Family Planning in Texas: Are Family Physicians Ready?

Bhavik Kumar, MD; Ariana Bennett, MPH; Arthur Blank, PhD; Marji Gold, MD

Marji Gold, MD

Curriculum Vitae

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Women's Experiences With Early Elective IUD Removal

Jennifer Amico, MPH, MD; Ariana Bennett, MPH; Marji Gold, MD; Alison Karasz, PhD

Patient Preferences for Contraceptive Counseling After Abortion

Aleza Summit, MPH; Lauren Casey, BA; Ariana Bennett, MPH; Alison Karasz, PhD; Marji Gold, MD

Developing Patient-Centered Teams: The Role of Sharing Stories About Patients and Patient Care

Ariana Bennett, MPH; Jane Hassinger; Lisa Martin; Lisa Harris; Marji Gold, MD

2015 Medical Students For Choice- Philadelphia, PA November 2015

Women Seeking Multiple Abortions: Provider Perspectives  
Lauren Casey, Marji Gold MD

Provider Panel

Cheryl Chastine MD, Lin Fan Wang MD, Marji Gold MD

2016 North American Primary Care Research Group

Evaluation of Video-based Curriculum Tool for Improving Education about

Long-Acting Reversible Contraception in Family Medicine Residencies

Integration of Onsite LARC services into school-based health centers

"You can't give this job away": Being a leader in abortion care

2016 Medical Students For Choice- Tucson AZ, November 2016

Contraceptive Counseling at the Time of Abortion: Provider Perspectives  
Rory Woodard, Marji Gold MD

2016 STFM Annual Meeting

The Copper IUD as Post-Coital Contraception: Addressing  
Access and Knowledge Gaps Erica Bishop, Marji Gold

Providers' Experiences with Early Elective IUD Removal  
Jenn Amico, Ari Bennett, Alison Karasz, Marji Gold

Marji Gold, MD

Curriculum Vitae

29

Conversations About Reproductive Coercion in Family Medicine Training Hilary Rosenstein, MD; Ariana Bennett, MPH; Sharon Phillips, MD, MPH; Marji Gold, MD

Pregnancy and Obesity: Offering respectful reproductive health care to all women in the face of weight stigma Aleza Summit, Hilary Rosenstein, Marji Gold

Video-based Learning Tool for Improving Education about Long-acting Reversible Contraception in Family Medicine Residencies Aleza Summit, Hannah Helmy, Miranda Dettmann, Marji Gold

Patient-centered contraceptive counseling in the context of abortion care Aleza Summit, Marji Gold, Allison Paul, Hannah Helmy, Lauren Casey

Is there a doctor in the house? A guide to challenging phone calls, for residents and preceptors Alison Paul, Kamini Geer, Marji Gold

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- 1992 Book Review of Women, Work, and Health published in Family Systems Medicine Vol. 10 No. 2
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Marji Gold, MD 1997	Curriculum Vitae	30
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# Exhibit 10

1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
Civil Rights Division Chief  
5 ANDREW R.W. HUGHES, WSBA #49515  
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10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
CYNTHIA HARRIS

1 I, Cynthia Harris, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I have worked in the Sexual and Reproductive Health field for  
5 almost 30 years - 7 years at the clinic level and 22 years at the state level. I have  
6 been the manager of the Sexual and Reproductive Health Program at the  
7 Washington State Department of Health for 10 years.

8 3. As manager of the Department of Health's Sexual and Reproductive  
9 Health Program, my responsibilities are to ensure access within available funding  
10 to contraceptive services, STI testing, STI treatment and other sexual and  
11 reproductive health services including abortion through contracts with providers  
12 throughout Washington State.

13 4. The most-recent year for which the Washington State Department  
14 of Health has finalized abortion-care data is 2021. In 2021, there were 15,968  
15 abortions among Washington residents, out of 100,340 reported pregnancies. In  
16 addition to abortions among Washington residents, 998 abortions were provided  
17 to non-residents who traveled from out of state. Non-residents seeking abortion  
18 care in Washington came from 41 states, as well as Guam and Canada, with the  
19 majority coming from Idaho (406), Oregon (330), and Alaska (51).

20 5. In 2021, 59% of the abortions provided in Washington were  
21 medication abortions.  
22



1           6.     The total number of Washington facilities that reported providing  
2 abortions in 2021 is 46. Of those facilities, 37 provided five or more abortions.

3           7.     DOH's Sexual and Reproductive Health Program contracts with 6  
4 agencies that have 34 of the 46 clinics that provide abortions in Washington.  
5 These contracts are part of DOH's public health mission to improve equitable  
6 access to affordable, quality abortion care services for low-income and  
7 underserved patients in Washington. The six agencies DOH contracts with are:  
8 Planned Parenthood Great Northwest, Hawai'i, Alaska, Indiana, Kentucky;  
9 Planned Parenthood of Greater Washington and North Idaho; Planned  
10 Parenthood Columbia Willamette; Mount Baker Planned Parenthood; Cedar  
11 River Clinics; and Equinox Primary Care.

12           8.     Of the 34 DOH-contracted abortion clinics, 22 are located in  
13 western Washington and 12 are located in eastern Washington (east of the  
14 Cascade Mountains). Of the 12 contracted clinics in eastern Washington, 11 are  
15 operated by Planned Parenthood Greater Washington Northern Idaho, and one is  
16 operated by Cedar River Clinics. Outside of these two important partners, DOH  
17 has not located providers with the resources, capacity, and willingness to provide  
18 abortion care services in the eastern part of the State.

19           9.     All of the 34 DOH-contracted registered abortion clinics in  
20 Washington provide medication abortions, with 31 offering medication abortions  
21 via telehealth.  
22



1           10. Twelve of the 34 DOH-contracted registered abortion clinics also  
2 provide procedural abortions. Of these 12 clinics that provide procedural  
3 abortions, 9 are in western Washington, all located on the I-5 corridor. Three  
4 DOH contracted abortion clinics provide procedural abortions in eastern  
5 Washington, with one clinic in Kennewick, one clinic in Spokane, and one clinic  
6 in Yakima. An additional procedural abortion site will open in Yakima in March  
7 2023.

8           11. Exhibit 1 is a map showing the 20 out of Washington's 39 counties  
9 that have registered abortion clinics that contract with DOH. Abortion service  
10 access points are saturated on the western side of the state while sites in the  
11 eastern and southern parts of Washington are most likely to serve patients from  
12 Idaho and Oregon respectively based on geographic location. Clinics offering  
13 both medication and procedural abortion are located further away from each other  
14 in eastern Washington, which can cause residents of those counties to travel  
15 longer distances to access care, especially depending on appointment availability.  
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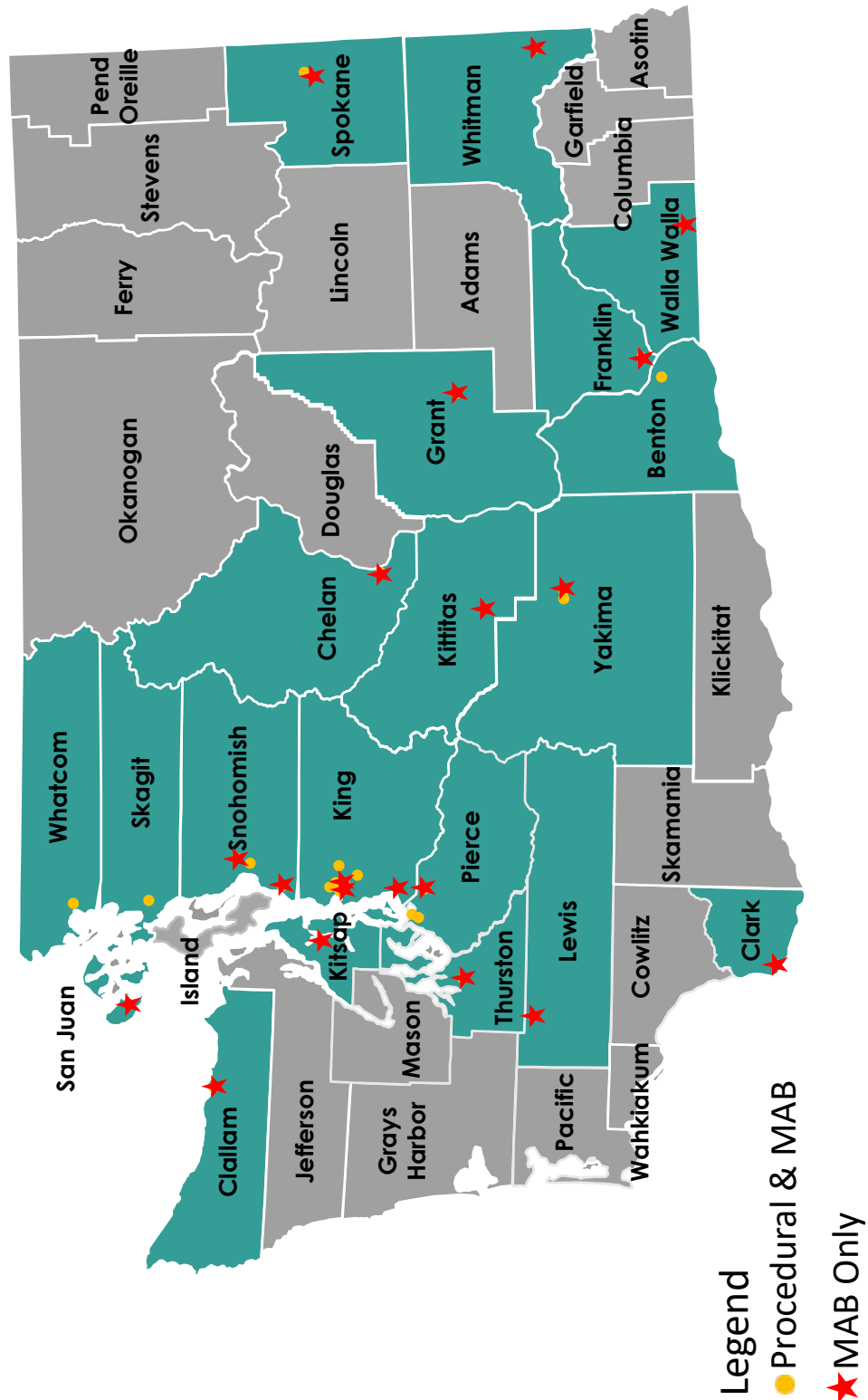
1 I declare under penalty of perjury under the laws of the State of  
2 Washington and the United States of America that the foregoing is true and  
3 correct.  
4

5 DATED this 21st day of February, 2023, at Mabton, Washington.

6   
7 CYNTHIA HARRIS  
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22

# Exhibit A

# Washington State Sexual & Reproductive Network Abortion Service Sites



# Exhibit 11

1 ROBERT W. FERGUSON  
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10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
SUNDAY HENRY, M.D.,  
GORDON HEDENSTROM, R.PH.,  
AND JOEL SCHWARTZKOPF

1  
2 Sunday Henry, Gordon Hedenstrom and Joel Schwartzkopf declare as  
3 follows:

4 1. I, Sunday Henry, am over the age of 18, am competent to testify as  
5 to the matters herein, and make this declaration based on my personal knowledge.  
6 I am a board certified family physician and Director of Medical Services at  
7 Cougar Health Services. I have provided healthcare services in rural Idaho and  
8 Washington State since 2008. I have a Bachelor degree from the University of  
9 Idaho, and received my medical degree from Creighton University School of  
10 Medicine. I completed a family medicine residency at the Family Medicine  
11 Residency of Idaho and completed a fellowship in Primary Care Sports Medicine  
12 thereafter. I am also the WSU Head Team Physician.

13 I, Gordon Hedenstrom, am over the age of 18, am competent to testify as  
14 to the matters herein, and make this declaration based on my personal knowledge.  
15 I am a board certified pharmacist and Pharmacy Director at Cougar Health  
16 Services. I have provided pharmacy services in Idaho and Washington including  
17 rural eastern Washington over the past 25 years. I received degrees in both  
18 Pharmacy and Business Administration from Washington State University. I  
19 have served in multiple healthcare positions including Branch Manager,  
20 Direction of Regional Operations and most recently, for the past 8 years, as  
21 Director of Pharmacy at CHS.  
22

1 I, Joel Schwartzkopf, am over the age of 18, am competent to testify as to  
2 the matters herein, and make this declaration based on my personal knowledge. I  
3 serve the students of WSU Pullman as the Assistant Vice Chancellor for Student  
4 Health and Wellbeing and as the Executive Director of Cougar Health Services.  
5 I received my Master of Physician Assistant Studies from the University of  
6 Nebraska Medical Center, my Master of Business Administration from Colorado  
7 State University, and my Bachelor of Science in Emergency Medical Services  
8 from Creighton University.

9 2. We are submitting this declaration in support of the State of  
10 Washington's motion for preliminary injunction.

11 3. Cougar Health Services (CHS) is a medical center located on the  
12 WSU Pullman Campus in Pullman, Washington. As an Accreditation  
13 Association for Ambulatory Health Care (AAAHC) accredited facility, CHS  
14 offers comprehensive services for preventative, on-going, and acute health needs.  
15 Our board-certified providers care for more than 10,000 individual WSU Pullman  
16 students each year in a variety of specialties, from sports medicine to gynecology  
17 to mental health. CHS pharmacy is a full-service pharmacy located inside the  
18 medical clinic on the WSU Pullman Campus.

19 4. CHS provides gynecological and sexual healthcare for WSU  
20 students on our Pullman campus. These services include birth control  
21 prescriptions, placement of intrauterine devices and birth control implants, and  
22



1 counseling on various methods of birth control; emergency contraception/Plan  
2 B; sexually transmitted infection testing, treatment and prevention; confirmation  
3 of pregnancy and episodic medical care for women who are pregnant.

4 5. CHS does not offer any type of abortion services for its students,  
5 including medication abortion. Instead, it refers students to other providers,  
6 including Planned Parenthood, whose closest clinics are in Pullman and Spokane.  
7 This referral process is time-sensitive and often creates an undue amount of stress  
8 for the student while they are attempting to access services.

9 6. We are familiar with mifepristone and the associated Risk  
10 Evaluation and Mitigation Strategy (REMS) program requirements when used  
11 for medication abortion, including the most recent January 2023 REMS. In our  
12 opinion, the REMS program requirements act as a barrier to the ability of WSU  
13 students to receive comprehensive reproductive health care services in a rural  
14 area.

15 7. In particular, CHS does not have any providers that are registered  
16 prescribers for mifepristone under the REMS program requirements and the CHS  
17 pharmacy is not an authorized pharmacy under the REMS program requirements.

18 8. Given the limited availability of reproductive health care services in  
19 this rural area, the requirements imposed by the January 2023 REMS act to  
20 further limit access to comprehensive reproductive health care services to patients  
21 in this community.  
22

1 We declare under penalty of perjury under the laws of the State of  
2 Washington and the United States of America that the foregoing is true and  
3 correct.

4 DATED this 21 day of February, 2023, at Pullman,  
5 Washington.

6 Sunday Henry MD  
7 Sunday Henry, MD

8 Gordon Hedenstrom R.Ph.  
9 Gordon Hedenstrom, R.PH.

10 Joel Schwartzkopf  
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DECLARATION OF  
HENRY, HEDENSTROM AND  
SCHWARTZKOPF

# Exhibit 12

1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
Civil Rights Division Chief  
5 ANDREW R.W. HUGHES, WSBA #49515  
LAURYN K. FRAAS, WSBA #53238  
6 Assistant Attorneys General  
TERA M. HEINTZ, WSBA #54921  
7 (application for admission forthcoming)  
Deputy Solicitor General  
8 800 Fifth Avenue, Suite 2000  
Seattle, WA 98104-3188  
9 (206) 464-7744

10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
ELIZABETH JANIAC, SCD,  
MSC, MA

1 I, Elizabeth Janiak, ScD, MSc, MA declare as follows:

2 1. I am over the age of 18. I make this declaration based on my own  
3 personal knowledge and am competent to testify as to the matters herein.

4 **A. Background and Qualifications**

5 2. I am an interdisciplinary researcher with expertise in sociology,  
6 epidemiology, and health systems research.

7 3. I am an Assistant Professor of Obstetrics, Gynecology and  
8 Reproductive Biology at Brigham and Women's Hospital / Harvard Medical  
9 School, and of Social and Behavioral Sciences at the Harvard T.H. Chan School  
10 of Public Health.

11 4. I graduated with a BA from Harvard College and earned an MA in  
12 American Studies from New York University. I completed an MSc in Society,  
13 Human Development, and Health and ScD in Social and Behavioral Sciences,  
14 both from the Harvard T.H. Chan School of Public Health. I received  
15 postdoctoral training at Brigham and Women's Hospital. I am a former recipient  
16 of the Society of Family Planning Research Fund's Junior Investigator Award.

17 5. My research explores how public policy and health system  
18 characteristics affect the availability and quality of contraceptive and abortion  
19 care in the United States. My research utilizes both qualitative and quantitative  
20 methods, particularly survey research, analysis of administrative data, and  
21

1 person-centered qualitative methods such as in-depth interviews and focus  
2 groups.

3 6. A copy of my curriculum vitae is attached hereto as Exhibit A.

4 7. I submit this declaration in support of Plaintiff's Motion for  
5 Preliminary Injunction. I do so only in my individual capacity, not on behalf of  
6 any institution with which I am affiliated.

7 8. I have been retained as an expert in this matter, and am being  
8 compensated at a rate of \$165 per hour.

9 **B. Expert Opinions**

10 9. The U.S. Food and Drug Administration ("FDA") submits  
11 mifepristone, a medication used for early abortion and miscarriage care, to a Risk  
12 Evaluation and Mitigation Strategy ("REMS") that, among other things, requires  
13 that mifepristone be dispensed by or under the supervision of a certified  
14 prescriber, or by certified pharmacies for prescriptions issued by certified  
15 prescribers, and the use of Prescriber (or Provider) and Patient Agreement forms.  
16 Updates permitting dispensing by certified pharmacies went into effect on  
17 January 3, 2023.

18 **1. Mifepristone's safety and efficacy have been established by**  
19 **robust empirical evidence.**

20 10. According to the National Academies of Sciences, Engineering and  
21 Medicine's landmark report, *The Safety and Quality of Abortion Care in the*  
22

1 *United States*, quality abortion care should be safe, effective, patient-centered,  
2 timely, efficient, and equitable.<sup>1</sup>

3 11. Based on my review of literature, I know that “mifepristone has  
4 been shown to have an excellent safety profile” and that “[a]bortion with  
5 mifepristone is safe and effective.”<sup>2</sup> For example, contemporary evidence-based  
6 medication abortion protocols using mifepristone and misoprostol have an  
7 efficacy rate of 97%.<sup>3</sup>

8  
9  
10 <sup>1</sup> *The Safety and Quality of Abortion Care in the United States*.

11 National Academies of Sciences, Engineering, and Medicine; Health and  
12 Medicine Division; Board on Health Care Services; Board on Population Health  
13 and Public Health Practice; Committee on Reproductive Health Services:  
14 Assessing the Safety and Quality of Abortion Care in the U.S.  
15 Washington (DC): National Academies Press (US); 2018 Mar 16.

16  
17 <sup>2</sup> Calloway D, Stulberg DB, Janiak E. *Mifepristone restrictions and primary care:  
18 Breaking the cycle of stigma through a learning collaborative model in the  
19 United States*. Contraception. 2021 July; 104(1):24-28.

20 <sup>3</sup> Chen M, Creinin MD. *Mifepristone with Buccal Misoprostol for Medical  
21 Abortion: a Systematic Review*. Obstet Gynecol 2015;126(1):12-21.  
22

12. Some individuals in need of pregnancy termination prefer medical treatment to procedural intervention such as manual vacuum aspiration.<sup>4</sup> Ensuring access to both procedural and medication abortion options is key to patient-centeredness of abortion care.

**2. The REMS have historically impeded access to mifepristone, impairing the timeliness, efficiency, and equity of abortion care.**

13. The regulatory regimes imposed by the FDA on mifepristone have consistently impeded access to this safe and effective treatment. In 2000, initial approval mandated use of a restricted distribution system. In 2007, HR3580 authorized the FDA to establish the REMS program, and a REMS program for mifepristone was imposed in 2011.

14. The advent of mifepristone held great potential to expand access to abortion services because a wide array of clinicians is well-qualified to prescribe the drug, including specialist and generalist obstetrician-gynecologists, as well as appropriately trained primary care physicians, family and women's health nurse practitioners, pediatricians, and physician assistants. Because primary care clinicians (n>300,000) vastly outnumber obstetrician-gynecologists (n=approx. 43,000) in the United States, and they are more likely

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<sup>4</sup>Ho PC. *Women's perceptions on medical abortion*. Contraception. 2006;74(1):11-5.



1 to practice in underserved and rural communities, integration of mifepristone  
 2 into primary care settings in particular could improve abortion care timeliness,  
 3 efficiency, and equity in the United States.<sup>5</sup>

4 15. The REMS program has impeded widespread provision of  
 5 mifepristone by generalist obstetrician-gynecologists and by primary care  
 6 clinicians. In studies among obstetrician-gynecologists in Massachusetts and  
 7 Alabama, my colleagues and I found that the REMS program constitutes a  
 8 major barrier to mifepristone use for generalist obstetrician-gynecologists.<sup>6</sup>  
 9 Further, my research original qualitative research with primary care clinicians  
 10

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11  
 12 <sup>5</sup> Association of American Medical Colleges. [Internet.] Physician Specialty Data  
 13 Report. Accessed 19 February 2023. Accessible at: [https://www.aamc.org/data-](https://www.aamc.org/data-reports/workforce/interactive-data/number-people-active-physician-specialty-2021)  
 14 [reports/workforce/interactive-data/number-people-active-physician-specialty-](https://www.aamc.org/data-reports/workforce/interactive-data/number-people-active-physician-specialty-2021)  
 15 2021.

16 <sup>6</sup> Neill S, Goldberg AB, Janiak E. "Medication Management of Early Pregnancy  
 17 Loss: The Impact of the US Food and Drug Administration Risk Evaluation and  
 18 Mitigation Strategy [A289]." *Obstet Gynecol* 2022 139 (2022): 83S; Mokashi  
 19 M, Boulineaux C, Janiak E, Boozer M, Neill S. "There's only one use for it":  
 20 Stigma as a Barrier to Mifepristone Use for Early Pregnancy Loss in Alabama.  
 21 [A31]. *Obstet Gynecol* 2022 139 (2022): 9S-10S.  
 22

1 in Illinois and several New England states found that individuals trained in and  
2 motivated to provide abortion care consistently cite the REMS as a major  
3 barrier.<sup>7</sup> Another recent nationwide study similarly concluded that the REMS  
4 program impedes mifepristone provision among trained clinicians who desire to  
5 integrate abortion services into their scope of practice.<sup>8</sup>

6 16. In my original research study, primary care clinicians specifically  
7 reported that being able to prescribe mifepristone in a manner similar to other  
8 drugs, for dispensing at a retail pharmacy, would facilitate provision of  
9 medication abortion.<sup>9</sup>

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11 <sup>7</sup>Calloway *supra* note 2; Lee CM, Johns SL, Stulberg DB, Allen RH, Janiak E.  
12 *Barriers to abortion provision in primary care in New England, 2019-2020: A*  
13 *qualitative study*. Contraception. 2023; 117:39-44.

15 <sup>8</sup> Razon N, Wulf S, Perez C, McNeil S, Maldonado L, et al. *Exploring the*  
16 *impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the*  
17 *integration of medication abortion into US family medicine primary care*  
18 *clinics*. Contraception 2022;109(5):19-24.

20 <sup>9</sup> Rasmussen KN, Janiak E, Cottrill AA, Stulberg DB. *Expanding access to*  
21 *medication abortion through pharmacy dispensing of mifepristone: Primary care*  
22 *perspectives from Illinois*. Contraception. 2021; 104(1):98-103.

1           **3. The January 2023 REMS program continues to impede access**  
 2           **to mifepristone**

3           17. The January 2023 REMS program for mifepristone continues to  
 4           impede access by continuing burdensome requirements from prior REMS and  
 5           adding additional burdensome requirements for pharmacies.

6           18. The January 2023 REMS requirement that prescribers register with  
 7           the drug manufacturer (the “Prescriber Agreement”) impedes access to  
 8           mifepristone in multiple ways.

9           19. Mifepristone (plus adjunctive misoprostol) is a safe, effective,  
 10          efficient and patient-centered intervention for miscarriage management as well  
 11          as abortion.<sup>10</sup> However, the association of mifepristone with abortion can make  
 12          it difficult to use for any indication.<sup>11</sup>

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13  
 14  
 15          <sup>10</sup> Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT.  
 16          *Mifepristone Pretreatment for the Medical Management of Early Pregnancy*  
 17          *Loss*. N Engl J Med 2018;378:2161-70; Chu JJ, Devall AJ, Beeson LE, Hardy  
 18          P, Cheed V, et al. *Mifepristone and misoprostol versus misoprostol alone for*  
 19          *the management of missed miscarriage (MifeMiso): a randomised, double-*  
 20          *blind, placebo-controlled trial*. Lancet. 2020; 396(10253): 770–778.

21  
 22          <sup>11</sup> Mokashi *supra* note 6.

20. By effectively requiring prescribers to register as potential abortion providers, and send those registrations to any pharmacies who may dispense mifepristone, the REMS program creates fear and stigmatization among prescribers. Given a history and ongoing practice of terroristic violence against abortion providers in the United States, individuals logically fear that the registration process mandated by the REMS could put them and their practices at risk.<sup>12</sup>

21. There is no need for a prescriber agreement to ensure safe dispensing of mifepristone, as has been demonstrated by data from Canada. Though Canadian regulations briefly included REMS-like restrictions including provider self-certification and dispensing restrictions, all such regulations were quickly removed after introduction of mifepristone in 2017. Canadian data demonstrate an excellent safety profile for normally prescribed mifepristone with no provider self-certification, including significantly lower rates of documented complications (0.69%) than found in most clinical trials of mifepristone.<sup>13</sup>

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<sup>12</sup> Cohen DS, Cannon K. *Living in the Crosshairs: The Untold Stories of Anti-Abortion Terrorism*. Oxford University Press: 2015.

<sup>13</sup> Schummers L, Darling EK, Dunn S, McGrail K, Gayowsky A, et al. *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*. N Engl J Med 2022;386:57-67.

22. The January 2023 REMS requirement that patients sign a specific form (the “Patient Agreement”) stating the drug will be used for a medication abortion is another requirement that impedes access to mifepristone. The Patient Agreement’s statement that mifepristone will be used for a medication abortion results in unnecessary confusion for patients given the evidence base that mifepristone is also effective for both early pregnancy loss treatment and cervical preparation prior to dilation and evacuation procedures.<sup>14</sup> Patients should not be mandated to sign a form that may contradict their own treatment plan.

23. The January 2023 REMS requirement that pharmacies must be certified by the manufacturer in order to dispense mifepristone is another requirement that impedes access to mifepristone. Based on my review of literature, there is no evidence that a pharmacy should have to be specially certified to dispense mifepristone and it is irrefutably clear that mifepristone can be safely prescribed through the typical avenues.<sup>15</sup> While conferring no benefit

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<sup>14</sup> Goldberg AB, Fortin JA, Drey EA, Dean G, Lichtenberg ES, et al. *Cervical Preparation Before Dilation and Evacuation Using Adjunctive Misoprostol or Mifepristone Compared With Overnight Osmotic Dilators Alone: A Randomized Controlled Trial*. *Obstet Gynecol*. 2015;126(3):599-609..

<sup>15</sup> Schummers *supra* note 13; Grossman D, Baba CF, Kaller S, Biggs MA, Raifman S, et al. *Medication Abortion with Pharmacist Dispensing of Mifepristone*. *Obstet Gynecol*. 2021;137(4):613-622.

1 to patient safety, the pharmacy certification requirement does burden pharmacists  
 2 and prescribers, impeding their ability to offer mifepristone. By compelling  
 3 pharmacies to become certified and to verify that all prescriptions they fill are  
 4 from a certified prescriber specifically registered as a mifepristone provider, the  
 5 REMS program creates administrative hurdles that may be difficult or impossible  
 6 for some pharmacies to negotiate.

7 **4. The 2023 REMS program for mifepristone perpetuates, health**  
 8 **inequities by race/ethnicity, gender, geography, age, and other**  
 9 **factors.**

10 24. People who receive abortion care in specialty reproductive health  
 11 clinics or via telemedicine are overwhelmingly very satisfied with their care.<sup>16</sup>  
 12 Nonetheless, according to research conducted in both abortion specialty clinic  
 13  
 14  
 15  
 16

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17 <sup>16</sup> Tilles C, Denny A, Cansino C, Creinin MD. *Factors influencing women's*  
 18 *satisfaction with surgical abortion*. Contraception. 2016;93(2):164-9; Meurice  
 19 ME, Whitehouse KC, Blaylock R, Chang JJ, Lohr PA. *Client satisfaction and*  
 20 *experience of telemedicine and home use of mifepristone and misoprostol for*  
 21 *abortion up to 10 weeks' gestation at British Pregnancy Advisory Service: A*  
 22 *cross-sectional evaluation*. Contraception. 2021;104(1):61-66.

1 settings and primary care settings, a majority of patients would prefer to receive  
2 abortion care in their usual site of care or from a known provider.<sup>17</sup>

3 25. Preference for receiving abortion care within a system where one is  
4 an established patient may be driven by a variety of factors, including a pre-  
5 existing, trusting relationship between patient and provider. Individuals who  
6 experience high distrust of medical settings, including people who identify as  
7 Black, Indigenous, or People of Color (BIPOC), may particularly benefit from  
8 integration of abortion services into settings where their trust as patients has  
9 already been earned. Moreover, individuals with unique clinical and social  
10 needs—such as individuals who do not speak English, persons with disabilities,  
11 trans, nonbinary, and gender nonconforming (TGNC) patients, and adolescents—  
12 may benefit from tailored models of care. For all patients, choice of care setting  
13 is paramount to patient-centeredness, a key attribute of quality abortion care.<sup>18</sup>

14 26. By preventing trained and willing clinicians from integrating  
15 mifepristone into their scope of practice, the 2023 REMS program eliminates or  
16 \_\_\_\_\_

17 <sup>17</sup> Godfrey EM, Rubin SE, Smith EJ, Khare MM, Gold M. *Women's preference*  
18 *for receiving abortion in primary care settings*. J Womens Health (Larchmt).  
19 2010;19(3):547-53; Rubin SE, Godfrey E, Gold M. *Patient attitudes toward early*  
20 *abortion services in the family medicine clinic*. J Am Board Fam Med.  
21 2008;21(2):162-4.

22 <sup>18</sup> National Academies *supra* note 1.

limits choice of abortion care setting for many. The burdens of lack of choice fall disproportionately on individuals who lack geographic access to abortion care providers, even in states where abortion remains broadly legal—as in many areas in the US Midwest and South, and rural locations.<sup>19</sup>

**5. The ability to access mifepristone via specially certified mail order pharmacies does not resolve access barriers imposed by the 2023 REMS program nor ameliorate its impacts on health inequities.**

27. Mailing mifepristone is a safe and effective service delivery model that may improve access to care for some patients.<sup>20</sup> However, mailed mifepristone is not a viable alternative to pharmacy dispensing for all individuals. In particular, people experiencing intimate partner violence (IPV) may not be able to safely receive abortion medications via mail. Reproductive coercion (RC) is a form of IPV that can include the behavior of coercing an individual to

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<sup>19</sup> Jones RK, Kirstein M, Philbin J. *Abortion incidence and service availability in the United States, 2020*. Perspect Sex Reprod Health. 2022;54(4):128-141.

<sup>20</sup> ARA Aiken ARA, Lohr PA, Lord J, Ghosh N, Starling J. *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*. BJOG 2021;128:1464-74.



1 continue a pregnancy against their will. While estimates of the prevalence of RC  
 2 vary widely, a recent study found 1 in 6 obstetrics and gynecology patients have  
 3 experienced RC.<sup>21</sup>

4  
 5 28. Other populations who may not be able to safely receive  
 6 mifepristone via mail include young people who must keep their pregnancy  
 7 private from family members. My research has found that though large majorities  
 8 of young people involve parents and other adult relatives in abortion decisions  
 9 and care-seeking, some individuals fear a pregnancy disclosure could precipitate  
 10 abuse, loss of housing, or withholding of financial resources.<sup>22</sup>

11  
 12 29. Mailed mifepristone is also not a substitute for pharmacy  
 13 dispensing for individuals experiencing housing insecurity and homelessness.  
 14 While the prevalence of homelessness among abortion patients specifically is not

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15  
 16 <sup>21</sup> Clark LE, Allen RH, Goyal V, Raker C, Gottlieb AS. *Reproductive coercion*  
 17 *and co-occurring intimate partner violence in obstetrics and gynecology*  
 18 *patients*. Am J Obstet Gynecol. 2014;210(1):42.e1-8.

19 <sup>22</sup> Tantoco NK, Goldberg AB, Sabino J, Janiak E. *“They would be disappointed”:*  
 20 *an analysis of minors’ motivations for seeking judicial bypass of Massachusetts’*  
 21 *parental consent requirement for abortion*. [Abstract.] Contraception  
 22 2017;96(4):276.

1 well documented, prior research found 1 in 8 abortion patients had moved  
2 multiple times in the prior year.<sup>23</sup> Abortion patients in the United States are  
3 disproportionately low-income and vulnerable to disruptive life events that  
4 threaten housing stability.  
5

## 6 **6. Conclusion**

7 30. To improve reproductive health care quality and equity, policies  
8 and health systems should endeavor to make abortion services available to  
9 patients in a wide variety of settings that can meet their diverse and unique needs.  
10 It is my expert opinion that removing the Patient Agreement Form, the Prescriber  
11 and Provider Agreements, and the pharmacy certification requirement currently  
12 imposed by the January 2023 REMS will significantly improve public health in  
13 the United States.  
14  
15  
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18

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19  
20 <sup>23</sup> Jones RK, Frohwirth L, Moore AM. *More than poverty: disruptive*  
21 *events among women having abortions in the USA*. J Fam Plann Reprod Health  
22 Care. 2013;39(1):36-43.

1 I declare under penalty of perjury under the laws of the State of  
2 Washington and the United States that the foregoing is true and correct.

3 DATED this 21st day of February, 2023, at Boston,  
4 Massachusetts.

5  
6   
Elizabeth Janiak, ScD, MSc, MA

# Exhibit A

**Elizabeth Janiak, ScD**[ejaniak@bwh.harvard.edu](mailto:ejaniak@bwh.harvard.edu) | 617-525-9686

Abbreviated Curriculum Vitae / NIH Biosketch Hybrid

**Education and Training**

INSTITUTION AND LOCATION	DEGREE	DATE	FIELD OF STUDY
Harvard College, Cambridge, MA	BA	06/2003	Comparative Study of Religion
New York University, New York, NY	MA	05/2007	American Studies
Harvard School of Public Health, Boston, MA	MSc	05/2011	Society, Human Development, and Health
Harvard T.H. Chan School of Public Health, Boston, MA	ScD	05/2016	Social and Behavioral Sciences
Brigham and Women's Hospital / Harvard Medical School, Boston, MA	Postdoctoral Research Fellowship	06/2017	Obstetrics, Gynecology and Reproductive Biology

**Faculty Appointments**

2017-2019	Instructor, Department of Obstetrics, Gynecology and Reproductive Biology, Brigham and Women's Hospital and Harvard Medical School
2017-2019	Instructor, Division of Women's Health, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School
2017-	Lecturer, Women's and Gender Studies, Massachusetts Institute of Technology
2018-2021	Instructor, Social and Behavioral Sciences, Harvard T.H. Chan School of Public Health
2019-	Assistant Professor, Department of Obstetrics, Gynecology and Reproductive Biology, Brigham and Women's Hospital and Harvard Medical School
2022-	Assistant Professor of Social and Behavioral Sciences, Harvard T.H. Chan School of Public Health

**Personal Statement**

I am an interdisciplinary social science researcher studying the impact of public policy and social determinants of health on access to and quality of abortion and contraceptive care in the United States. Broadly, my research explores how dynamics of social inequality affect just and equitable reproductive healthcare access. My methodological expertise includes qualitative research, causal inference for observational data sets, and survey design. I use an intersectional approach to analyze how inequities in reproductive health outcomes according to race, gender, sexual orientation, geography, dis/ability, and socioeconomic class are produced. I also design and evaluate structured interventions to improve reproductive health care quality. I am particularly interested in the role of social stigma and conscious and unconscious bias in shaping health outcomes. Ongoing and recent projects that I would like to highlight include:

R21 HD103977

Janiak (PI)

07/2021-06/2023

National Institute for Child Health and Human Development, *Birth Control to Improve Birth Spacing (BIBS)*  
Sequential mixed-methods study of drivers of postpartum contraceptive use.

R01 AA030529

Hall and Welsh (MPIs); Janiak Role: Site PI, co-investigator

09/2022-08/2027

National Institute on Alcohol Abuse and Alcoholism, *Improving alcohol and substance use care access, outcomes, and equity during the reproductive years: A Type 1 Hybrid Trial in Family Planning Clinics*

Irving Harris Foundation and Large Anonymous Donor  
 Janiak and Stulberg (Co-PIs)  
 01/2019-12/2024

*Expanding Access to Mifepristone in Primary Care Settings*

Mixed-methods implementation science and efficacy study of two interventions to identify and ameliorate barriers to evidence-based use of mifepristone for abortion and miscarriage care.

Massachusetts Executive Office of Health and Human Services

White (PI), Janiak Role: Site PI, co-investigator

10/2018-09/2023

*Partners in Contraceptive Choice and Knowledge (PICCK)*

Research and evaluation embedded in a technical assistance program for Massachusetts birth hospitals to improve quality and scope of contraceptive care.

Selected Citations (chronological order):

- a. **Janiak E**, Goldberg AB. Eliminating the phrase "elective abortion": why language matters. *Contraception*. 2016;93(2):89-92.
- b. Mallampati D, Simon MA, **Janiak E**. Evolving state-based contraceptive and abortion policy. *JAMA* 2017;317(24):2481-2482.
- c. Smith BEY, Bartz D, Goldberg AB, **Janiak E**. "Without any indication": stigma and a hidden curriculum within medical students' discussion of elective abortion. *Soc Sci Med*. 2018;10(214):26-34.
- d. **Janiak E**, Fulcher IR, Cottrill AA, Tantoco N, Mason AH, Fortin J, Sabino J, Goldberg AB. Massachusetts' Parental Consent Law and Procedural Timing Among Adolescents Undergoing Abortion. *Obstet Gynecol*. 2019;133(5):978-986.
- e. Calloway D, Stulberg DB, **Janiak E**. Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States. *Contraception*. 2021;104(1):24-28.
- f. Fulcher IR, Onwuzurike C, Goldberg AB, Cottrill AA, Fortin J, **Janiak E**. The impact of the COVID-19 pandemic on abortion care utilization and disparities by age. *Am J Obstet Gynecol*. 2022;226(6):819.e1-819.e15
- g. Ravi K, **Janiak E**. Adverse pregnancy outcomes: biological essentialism versus embodied biology. *Lancet*. 2022 05 28; 399(10340):2013-2014.

## B. Positions, Scientific Appointments, and Honors

### Positions and Non-faculty Scientific Appointments

2007-	Member, Abortion Access Steering Committee, Massachusetts Department of Public Health
2007-2009	Case Manager, Massachusetts Abortion Access Program at Planned Parenthood League of Massachusetts
2011-	Member, American Public Health Association
2011-2014	Member, Association of Reproductive Health Professionals
2013-2017	Junior Fellow, Society of Family Planning
2014-2017	Junior Fellows Committee, Society of Family Planning
2016-	Director of Social Science Research, Planned Parenthood League of Massachusetts
2017	Co-chair, Trainee Grant Review Committee, Society of Family Planning Research Fund
2017-2021	Elected Faculty Representative in Population Health, Research Oversight Committee, Brigham Research Institute, Brigham and Women's Hospital
2018-	Full Fellow, Society of Family Planning
2019-2020	Member, Annual Meeting Committee, Society of Family Planning Research Fund
2020	Grant Reviewer, Fellowship in Complex Family Planning
2021	Grant Reviewer, Robert Wood Johnson Foundation, Health Data for Action grants
2016-	<i>Ad hoc</i> Reviewer (selected): <i>American Journal of Public Health</i> , <i>Contraception</i> , <i>Health Equity</i> , <i>Historical Methods</i> , <i>Journal of Health and Social Behavior</i> , <i>Perspectives on Sexual and Reproductive Health</i> , <i>PLoS ONE</i> , <i>Social Science and Medicine – Population Health</i>
2023-	Associate Editor, <i>Contraception and Reproductive Medicine</i>

**Honors**

1999-2002	John Harvard Scholarship for Academic Distinction
2003	Graduated <i>summa cum laude</i> , Harvard College, Cambridge, MA
2003	Elected <i>Phi beta kappa</i> , Alpha Iota of Massachusetts, Harvard College, Cambridge, MA
2004-2007	MacCracken Fellow, tuition, stipend, and research grant, New York University, New York, NY
2009-2010	Lowney Memorial Scholarship, Planned Parenthood League of Massachusetts, Boston, MA
2009-2011	Pforzheimer Public Service Fund tuition grant, Harvard School of Public Health, Boston, MA
2012-2013	Seiden Denny Scholarship and Stipend, for excellence in maternal and child health, Harvard School of Public Health, Boston, MA
2013-2014	Institutional Tuition Grant, Harvard School of Public Health, Boston, MA
2013	Population, Reproductive, and Sexual Health Section Student Scholarship, for outstanding commitment to sexual and reproductive health, American Public Health Association Annual Meeting, Boston, MA
2014-2015	Junior Investigator Award, Society of Family Planning Research Fund, SFPRF8-JI1
2014-2016	Maternal and Child Health/Children, Youth, and Families Interdepartmental Concentration Award, tuition grant and stipend, Harvard T.H. Chan School of Public Health, Boston, MA
2018-2021	Eleanor and Miles Shore 50 <sup>th</sup> Anniversary Award for Scholars in Medicine, salary and research support, Harvard Medical School

**C. Contribution to Science**

- a. Analyzing how social norms and attitudes affect access to and experiences of reproductive health care. To explore the mechanisms through which *interpersonal and individual level* barriers to reproductive health care operate, I have developed a body of research grounded in behavioral theory. This includes both qualitative studies to probe how stigma affects health care professionals and patients, as well as quantitative studies using validated psychometric scales. My research highlights how social norms drive interest in and ability to obtain reproductive health services, affecting care-seeking behavior and driving experiences of interpersonal discrimination in health care settings. However, social norms and their relative impact on access to care are profoundly shaped by intersecting dynamics of power and oppression related to gender identity, racial and ethnic identity, and socioeconomic position.
  - a. **Janiak E**, Freeman S, Maurer R, Berkman LF, Goldberg AB, Bartz D. Relationship of job role and clinic type to perceived stigma and occupational stress among abortion workers. *Contraception* 2018;98(6):517-521.
  - b. Smith BEY, Bartz D, Goldberg AB, **Janiak E**. "Without any indication": stigma and a hidden curriculum within medical students' discussion of elective abortion. *Soc Sci Med*. 2018;10(214):26-34.
  - c. Agénor M, Cottrill AA, Kay E, **Janiak EF**, Gordon AR, Potter J. Contraceptive Beliefs, Decision Making and Care Experiences Among Transmasculine Young Adults: A Qualitative Analysis. *Perspect Sex Reprod Health*. 2020;52(1):7-14.
  - d. **Janiak E**, Braaten KP, Cottrill AA, Fulcher IR, Goldberg AB, Agénor M. Gender diversity among aspiration-abortion patients. *Contraception*. 2021;103(6):426-427.
  - e. Merz AA, **Janiak E**, Mokashi M, Allen RH, Jackson C, Berkowitz L, Steinauer J, Bartz D. "We're called upon to be nonjudgmental": A qualitative exploration of US medical students' discussions of abortion as a reflection of their professionalism. *Contraception*. 2022;106(2):57-63.
- b. Illuminating how health systems characteristics affect reproductive health care quality. My body of work at the *health systems level* focuses on understanding drivers of care quality across domains of timeliness, safety, and patient-centeredness. Using survey data and a variety of administrative sources including the electronic medical record (EMR), paper-based medical charts, and on-the-shelf data from case management programs, my research has found that patients face multiple barriers to quality care including gaps in physician knowledge and inconsistent access to high-quality referrals. These gaps in quality often fall disproportionately on individuals using public insurance and individuals who identify as people of color.
  - a. Holt K, **Janiak E**, McCormick MC, Lieberman E, Dehlendorf C, Kajeepeta S, et al. Pregnancy options counseling and abortion referrals among United States primary care physicians: results from a national survey. *Family Medicine*. 2017;49(7):527-536.



- b. Ho S, **Janiak E**. Impact of a case management programme for women seeking later second-trimester abortion: the case of the Massachusetts Access Program. *BMJ Sex Reprod Health*. 2018 Jul 14.
  - c. Maistrellis E, **Janiak E**, Hammel R, Hurwitz S, Delli-Bovi L, Bartz D. Demographic, Clinical, and Counseling Factors Associated with the Selection of Pregnancy Termination Method in the Second Trimester for Fetal and Pregnancy Anomalies. *Women's Health Issues*. 2019; 29(4):349-355.
  - d. **Janiak E**, Clark J, Bartz D, Langer A, Gottlieb B. Barriers and Pathways to Providing Long-Acting Reversible Contraceptives in Massachusetts Community Health Centers: A Qualitative Exploration. *Perspect Sex Reprod Health*. 2018;50(3):111-118.
  - e. Cottrill AA, Fulcher IR, Goldberg AB, Sabino J, Fortin J, **Janiak E**. Time Trends in Massachusetts Adolescents' Postabortion Contraceptive Uptake. *J Adolesc Health*. 2021; 68(2):364-369.
- c. Describing how policy-level factors influence access to reproductive health care. I have conducted original research to understand how *state and federal laws and regulations* impact access to reproductive healthcare, including through modeling studies, EMR analyses, and qualitative research. Additionally, I have published policy analyses in high-impact journals such as *JAMA*. My research has found that it is imperative to understand the interplay of federal and state policies to correctly characterize their combined influence on health care access and health outcomes.
- a. **Janiak E**, O'Donnell J, Holt K. Proposed Title X Regulatory Changes: Silencing Health Care Providers and Undermining Quality of Care. *Womens Health Issues*. 2018; 28(6):477-479.
  - b. Foley O, **Janiak E**, Dutton C. Women's decision making for postpartum sterilization: does the Medicaid waiting period add value? *Contraception*. 2018;98(4):312-316.
  - c. **Janiak E**, Fulcher IR, Cottrill AA, Tantoco N, Mason AH, Fortin J, Sabino J, Goldberg AB. Massachusetts' Parental Consent Law and Procedural Timing Among Adolescents Undergoing Abortion. *Obstet Gynecol*. 2019;133(5):978-986.
  - d. Fulcher IR, Neill S, Bharadwa S, Goldberg AB, **Janiak E**. State and federal abortion restrictions increase risk of COVID-19 exposure by mandating unnecessary clinic visits. *Contraception*. 2020; 102(6):385-391.
  - e. **Janiak E**, Belizaire C, Liu J, Fulcher IR. The association of U.S. state-level abortion restrictions with medication abortion service delivery innovations during the early COVID-19 pandemic. *Contraception*. 2022;113(9):26-29.

Link to full list of publications (41 indexed publications as of January 2023):

<http://www.ncbi.nlm.nih.gov/pubmed/?term=janiak+e>

#### D. Contribution to Teaching

- a. Reproductive Health, Rights, and Justice course design (2018). Created novel course for the Harvard Chan School's Women, Gender, and Health scholarly concentration. Course compares and contrasts perspectives on reproduction from biomedical, human rights, and reproductive justice paradigms, drawing on historical, epidemiological, and sociological literature. Original course, unique within the school, approved by faculty committee, full departmental faculty, and schoolwide curriculum committee through rigorous multistep process.
- b. Anti-Racism in OB/GYN: from Knowledge to Action course design (2020). Created a lecture series on anti-racist knowledge and practices for faculty and trainees in BWH Obstetrics and Gynecology. Course includes speakers of national renown and covers foundational knowledge and skill-building in the realms of research, care delivery, and advocacy.

#### E. Selected Additional Funding, 2017-present

Fellowship in Complex Family Planning Grant

Janiak (PI); Trainee PI: Sara Neill, MD, MPH

07/2019-06/2021

*Mifepristone use among Massachusetts obstetrician-gynecologists*



Mixed-methods exploration of barriers to and facilitators of mifepristone use for early pregnancy loss and abortion among generalist OB/GYNs.

SFPRF12-II4, Society of Family Planning Research Fund  
Janiak (PI)  
10/2017-05/2021

*Abortion Stigma Reduction at the Population Level: Development of a Mass Media Intervention*

Public health researchers and practitioners have partnered to improve population health by combating stigma around myriad health issues. Our study uses this approach to develop evidence-based messaging and to test its efficacy in reducing abortion stigma.

SFPRF11-01, Society of Family Planning Research Fund  
Braaten (PI); Role: Co-investigator  
10/2017-09/2020

*Understanding and Addressing the Needs of Abortion Patients Who Use Opioids: A Mixed-Methods Study*

This mixed-methods study explored abortion experiences and care quality among women who use opioids, with a focus on pain management, post-abortion contraceptive needs, and stigma reduction.

Brigham Care Redesign Incubator Start-Up Program  
Janiak (Co-PI with Candace Feldman, MD, ScD)  
01/2017-12/2018

*Screening to Understand Pregnancy Preferences and Offer Referrals and Treatment (SUPPORT)*

Intervention uses reproductive life planning screening question and referral pathways to contraceptive and preconception care to address disparities in health outcomes for women with systemic rheumatic disease.

SFPRF10-1, Society of Family Planning Research Fund  
Janiak (PI)  
10/2016-09/2018

*Describing the impact of parental involvement laws for minors seeking abortion care: the case of Massachusetts*

Retrospective review of clinical records and legal referral information for over 2,000 minors seeking abortion.

**F. Selected Invited Lectures and Abstracts, 2017-present**

- 2017 "Hospital Culture and Abortion Stigma: How Institutional Policies and Climate Affect Patient Care" (invited presentation) North American Forum on Family Planning, Atlanta, GA
- 2017 "State-level Abortion Restrictions: History, Trends, and Evidence of Impact" (Grand Rounds) Department of Obstetrics and Gynecology, Beth Israel Deaconess Medical Center
- 2018 "Abortion Care for Individuals who Use Opioids" (Lecture) Abortion Seminar, University of California San Francisco
- 2018 "A Clinical Pathway Model for Effective Referrals for Long-Acting Reversible Contraception" (invited roundtable) American Public Health Association Annual Meeting, San Diego, CA
- 2018 "Improving Reproductive Health Care for Women with Systemic Rheumatic Disease" (Grand Rounds) Division of Rheumatology, BWH
- 2018 "Geographies of Inequality: State-level Abortion Restrictions in the United States" (lecture) Willows Reproductive Health Speaker Series, Dept of Global Health and Population, Harvard Chan School
- 2020 "Intersectionality: a Practical Primer for Reproductive Health Research" (Grand Rounds) Department of Obstetrics and Gynecology, BWH
- 2021 "Contraceptive autonomy among pregnancy-capable individuals with disabilities" (lecture) Disability and Disparities Seminar, Lurie Institute for Disability Policy, Brandeis University
- 2021 "Public Health Implications of Texas Senate Bill Eight's Abortion Ban" (panel) Boston College Law School
- 2022 "Geographies of Inequality: How Increasing Abortion Restrictions Affect Population Health in the United States" (lecture) Course: Advancing Women's Health: A 2022 Update / Department of Medicine, BWH
- 2022 "Reproductive Autonomy and Abortion" (lecture series) University of Global Health Equity, Kigali, Rwanda

# Exhibit 13

1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
Civil Rights Division Chief  
5 ANDREW R.W. HUGHES, WSBA #49515  
LAURYN K. FRAAS, WSBA #53238  
6 Assistant Attorneys General  
TERA M. HEINTZ, WSBA #54921  
7 (application for admission forthcoming)  
Deputy Solicitor General  
8 800 Fifth Avenue, Suite 2000  
Seattle, WA 98104-3188  
9 (206) 464-7744

10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
JUDY LAZARUS

1 I, Judy Lazarus, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am a Certified Nurse-Midwife with Neighborcare Health, where I  
5 am a clinician in full scope practice. I am a Doctor of Nursing Practice (DNP),  
6 Advanced Registered Nurse Practitioner (ARNP), and Fellow of the American  
7 College of Nurse-Midwives (FACNM).

8 3. In addition to my full scope clinical practice, I was a midwifery  
9 educator at the University of Washington in the School of Nursing, Department  
10 of Child, Family, and Population Health Nursing for 20 years. I retired from  
11 teaching in [2020]. During my teaching career, I served as Chair of the American  
12 College of Nurse-Midwives Preceptor Development and Support Committee for  
13 the Clinical and Academic Educators Committee.

14 4. Neighborcare Health's mission is to provide comprehensive health  
15 care to families and individuals who have difficulty accessing care; respond with  
16 sensitivity to the needs of our culturally diverse patients; and advocate and work  
17 with others to improve the overall health status of the communities we serve. As  
18 an organization, our values are social justice, cultural sensitivity, community, and  
19 excellent care and service to our patients and community.

20 5. Neighborcare Health serves communities and patients who are  
21 underserved by the larger health care system and who face barriers to accessing  
22

1 high-quality health care. In 2021, 80% of the patients Neighborcare Health served  
2 were individuals living at or below the federal poverty level. The same year, 73%  
3 of our patients were either insured by Medicaid or uninsured. Our patients are  
4 racially and ethnically diverse, with approximately 89% of our midwifery  
5 patients self-identifying as members of a minority racial or ethnic group. In 2021,  
6 we served 27% of our patients in a language other than English.

7 6. Neighborcare Health operates clinics, mostly in greater Seattle and  
8 King County area. We operate 12 medical clinics, 7 dental clinics, 14 school-  
9 based health centers, 3 homeless and housing clinics, and 5 pharmacies.

10 7. Neighborcare Health is a federally qualified health center (FQHC),  
11 a federal designation applicable to community-based health organizations that  
12 qualify for federal funding in order to provide primary care and preventive care  
13 services to individuals regardless of their ability to pay. FQHCs like  
14 Neighborcare Health are a critical part of the nation's health care safety net.

15 8. Federal law does not permit FQHCs to use federal funds, either  
16 directly or indirectly, to provide abortion services. Accordingly, Neighborcare  
17 Health provides no abortion services at any of its clinics or locations.

18 9. Neighborcare Health routinely treats patients who are experiencing  
19 early pregnancy loss, sometimes referred to as miscarriage. Early pregnancy loss  
20 is common and occurs in approximately one out of every 10 known pregnancies.  
21  
22

1           10. Mifepristone is a drug that is safe and effective for use in treating  
2 early pregnancy loss that occurs up to 12 weeks gestation. Using a two-drug  
3 regimen, which is the gold-standard of care, a patient experiencing early  
4 pregnancy loss is prescribed one dose of mifepristone and one dose of  
5 misoprostol. A patient first takes mifepristone, which blocks the hormone  
6 progesterone, a hormone necessary to maintain the interior of the uterus. Between  
7 24 and 48 hours later, the patient then takes misoprostol, which causes cramping  
8 and bleeding to expel the contents of the uterus. This process completes the  
9 miscarriage.

10           11. Decades of evidence demonstrate that use of mifepristone, followed  
11 by misoprostol, to treat early pregnancy loss is both safe and effective.

12           12. While misoprostol can be used alone for the medical management  
13 of early pregnancy loss, a combination of misoprostol and mifepristone has been  
14 proven to be much more effective in the management of early pregnancy loss.  
15 When used alone, misoprostol has a rate of 67% for complete expulsion of  
16 pregnancy products two days after the medication is taken. The addition of  
17 mifepristone to medical management of early pregnancy loss increases the rate  
18 of completion after two days up to 84%. A 2018 randomized controlled trial  
19 comparing mifepristone and misoprostol to misoprostol alone, confirmed that the  
20 combination is more efficacious with a 25% increase in completion of the  
21 expulsion of products of conception. In addition, the study noted that the  
22

1 combination was associated with a 37% decreased risk of the need for uterine  
2 aspiration to complete treatment. Reports of adverse events were rare in both  
3 groups and experiences of bleeding intensity, pain, and adverse events were the  
4 same in the combination group as with misoprostol alone.

5 13. The availability of mifepristone to treat early pregnancy loss has  
6 advantages for patients and health care providers. For patients, use of  
7 mifepristone to treat early pregnancy loss allows them to be at home, in a setting  
8 under their control, when they experience cramping, bleeding, and the passing of  
9 the uterine contents. The procedural alternative of evacuation requires a patient  
10 to come to a clinic and undergo a vaginal procedure. For many patients, the  
11 evacuation procedure is experienced as traumatic and invasive, and co-occurs at  
12 a time of pregnancy loss that may already be traumatic for patients.

13 14. For clinics, use of mifepristone to treat early pregnancy loss frees  
14 clinic space, equipment, providers, and staff to treat patients and conditions that  
15 cannot be treated outside the clinical setting. For organizations like ours  
16 committed to treating as many patients in need of care as possible, the use of  
17 mifepristone to treat early pregnancy loss has clear upsides for patient access and  
18 health equity.

19 15. I am familiar with the amended Risk Evaluation and Mitigation  
20 Strategy (REMS) on prescribing and dispensing mifepristone, which took effect  
21 on January 3, 2023.  
22

1           16. The REMS includes requirements that mifepristone be dispensed by  
2 or under the supervision of a certified prescribers. Practitioners must sign a  
3 Prescriber Agreement form to become certified by the drug's manufacturer.  
4 Requiring providers to be specially certified will reduce the number of providers  
5 who will be able to prescribe mifepristone to treat early pregnancy loss. For  
6 example, family practice doctors who treat early pregnancy loss a couple of times  
7 a year are less likely to be able to devote the time to getting credentialed to  
8 prescribe mifepristone. This may mean that a patient experiencing early  
9 pregnancy loss will need to see someone other than their usual, trusted provider  
10 at a time when they may already be experiencing significant trauma. Simply put,  
11 when a medication is harder than usual to prescribe—even when it is the  
12 evidence-based standard of care—fewer providers will be able to prescribe it,  
13 even if they would like to.

14           17. The REMS also includes a requirement that mifepristone be  
15 dispensed only by specially certified pharmacies. This is a significant practical  
16 obstacle for community pharmacies and the patients who use them. Because of  
17 the REMS, fewer pharmacies will become certified, and patients will have to  
18 search farther to find a specially certified pharmacy. For patients like ours, many  
19 of whom do not own a car, do not speak English, or have work schedules or  
20 family obligations that do not allow them to spend time during the day searching  
21 for a specially certified pharmacy, this barrier imposed by the REMS means that  
22



1 they would be less likely to be able to get a mifepristone prescription filled, even  
2 if their provider prescribed it.

3 18. The REMS also require a patient receiving mifepristone to sign a  
4 Patient Agreement Form. The form states near the top “I have decided to take  
5 mifepristone and misoprostol to end my pregnancy.” Patients experiencing early  
6 pregnancy loss do not “decide” to end their pregnancies, and this language is an  
7 inaccurate and harmful REMS requirement, given how commonly mifepristone  
8 is prescribed for early pregnancy loss. In my own practice, if Neighborcare  
9 Health develops the ability to prescribe and dispense mifepristone, I will need to  
10 spend significant time counseling patients regarding the language on this form,  
11 and how it relates to the use of mifepristone for early pregnancy loss.


12 19. Notwithstanding Neighborcare Health’s commitment to delivering  
13 evidence-based, high-quality health care, we are currently unable because of the  
14 REMS to offer mifepristone to treat early pregnancy loss. If mifepristone did not  
15 carry a REMS, I am confident that Neighborcare Health providers would already  
16 be prescribing mifepristone and working to help our patients access it.

17 20. In partnership with one of my colleagues in Neighborcare Health’s  
18 clinical midwifery practice, Jessica Burke-Lazarus, I have been working on a care  
19 delivery proposal that would allow Neighborcare Health to prescribe and  
20 dispense mifepristone to treat early pregnancy loss. Because of the heightened  
21 training, compliance, recordkeeping, and other requirements of the mifepristone  
22

1 REMS, it will take months of work before Neighborcare Health will be able to  
2 make a final decision about whether it will be able to offer mifepristone  
3 consistent with the REMS, while meeting all of our other legal and patient-care  
4 standards. Even if our proposal is approved, it will take significant work to  
5 develop and implement the administrative and compliance systems that would be  
6 necessary to comply with the REMS. All of this time would be better devoted to  
7 serving Neighborcare Health's patients and working to reduce health disparities  
8 for the diverse communities we serve.

9  
10 I declare under penalty of perjury under the laws of the State of  
11 Washington and the United States of America that the foregoing is true and  
12 correct.

13 DATED this 21st day of February, 2023, at Seattle, WA.

14  
15   
16 Judy Lazarus  
DNP, CNM, ARNP, FACNM

# Exhibit 14

1 ELLEN F. ROSENBLUM  
Attorney General  
2 SANDER MARCUS HULL #35986  
Senior Assistant Attorney General  
3 YOUNGWO JOH, OSB # 164105 (*pro hac vice* forthcoming)  
Assistant Attorney General  
4 Oregon Department of Justice  
1162 Court Street NE  
5 Salem, OR 97301-4096  
Telephone: (503) 947-4700  
6 Email: marcus.hull@doj.state.or.us  
youngwoo.joh@doj.state.or.us  
7 *Attorney for State of Oregon*

8 **UNITED STATES DISTRICT COURT**  
**EASTERN DISTRICT OF WASHINGTON**

9 STATE OF WASHINGTON *et al.*,  
10  
11 Plaintiffs,

12 v.

13 UNITED STATES FOOD AND  
DRUG ADMINISTRATION;  
14 ROBERT M. CALIFF, in his official  
capacity as Commissioner of Food  
and Drugs; UNITED STATES  
15 DEPARTMENT OF HEALTH AND  
HUMAN SERVICES; and XAVIER  
16 BECERRA, in his official capacity as  
Secretary of the Department of  
17 Health and Human Services,  
18 Defendants.

NO. \_\_\_\_\_

DECLARATION OF  
MARK D. NICHOLS, M.D.

(In support of Motion for  
Preliminary Injunction)

19  
20 I, Mark D. Nichols, hereby declare:

21 1. I am over the age of 18, am competent to testify as to the matters in  
22 this declaration, and make this declaration based on my personal knowledge.

DECLARATION OF  
MARK D. NICHOLS, M.D.

1           2.     I make this declaration in support of Plaintiffs' Motion for  
2 Preliminary Injunction.

3           3.     I have over 40 years of experience as a medical provider in the  
4 field of obstetrics and gynecology. Additionally, I have performed medical  
5 research and published peer-reviewed papers in the field of family planning,  
6 with a particular focus on surgical and medication abortion, emergency  
7 contraception, and hormonal contraception.

8           4.     I received my Doctor of Medicine from the University of  
9 California, Davis in 1979. I completed my residency in obstetrics and  
10 gynecology at the Oregon Health & Science University in 1983. Since  
11 completing my residency, I have been an assistant professor, associate  
12 professor, and professor at OHSU. Since 2022, I have held the title of Emeritus  
13 Professor at OHSU.

14           5.     I am board-certified by the American Board of Obstetrics and  
15 Gynecology, and I am an Elected Fellow of the American College of Obstetrics  
16 and Gynecology. I have also held numerous elected and appointed positions in  
17 professional organizations dedicated to family planning.

18           6.     I have been licensed to practice medicine in Oregon since 1981,  
19 under license no. MD12638. From 1988 to 2013, I was the Chief of the  
20 Division of General Gynecology and Obstetrics at OHSU. Since 1988, I have  
21 been a director, co-director, and Director Emeritus of the Family Planning  
22 Fellowship at OHSU.

DECLARATION OF  
MARK D. NICHOLS, M.D.

1           7.     From 1994 to 2011, I was the Medical Director of Planned  
2     Parenthood Columbia Willamette Affiliate. I have also been a family planning  
3     consultant for the Oregon Health Authority, a consultant for Medecins sans  
4     Frontieres, Safe Abortion Care, and a consultant, visiting professor, and  
5     obstetrician for various family planning programs and services in other  
6     countries.

7           8.     I have authored or co-authored 68 peer-reviewed published papers  
8     in the field of obstetrics and gynecology. Of those papers, 22 relate to  
9     contraception, 32 relate to abortion care generally, 9 relate to medication  
10    abortion with mifepristone and misoprostol, including 6 addressing the medical  
11    outcomes of medication abortion.

12          9.     As a medical provider in the Department of Obstetrics and  
13    Gynecology at OHSU, my practice included the full range of obstetric and  
14    gynecologic care including office visits, prenatal care, delivering babies and  
15    performing gynecologic surgery. As part of my practice, I regularly prescribed  
16    medications for miscarriage care and for medication abortions. Those  
17    medications included mifepristone. I also supervised the use and prescription of  
18    medication for miscarriage management and medication abortions by other  
19    medical professionals in the Department, including by other physicians, nurse  
20    practitioners, midwives, physicians' assistants, and residents.

21          10.    Since 2022, I have been retired from my position as a medical  
22    provider at OHSU, but I continue to work with Planned Parenthood, including

1 to provide medication abortion services. I also work with the Lilith Clinic in  
2 Portland to provide, among other things, medication abortion services.

3 11. As a medical provider at Planned Parenthood and the Lilith Clinic,  
4 I continue to prescribe and supervise the use and prescription of mifepristone  
5 for miscarriage management and medication abortion purposes.

6 12. In my career, I have supervised several thousand medication  
7 abortions, nearly all of which were effected through the prescription of  
8 mifepristone with misoprostol.

9 13. Attached as **Exhibit A** is a copy of my current curriculum vitae.

10 14. I have particular expertise with the drug mifepristone. I was the  
11 principal investigator of the Population Council funded clinical trial for the  
12 Portland site. This work led to the FDA's approval of mifepristone. From 1994  
13 to 2000, I studied the medical outcomes of medication abortion via mifepristone  
14 through both clinical studies and closely following the medical literature on this  
15 topic.

16 15. As an obstetrician and gynecologist, I prescribed mifepristone for  
17 my patients and have done so since 1999, after it was approved by the U.S.  
18 Food & Drug Administration.

19 16. Mifepristone is one of a two-drug regimen prescribed for  
20 medication abortions and miscarriage management. The drug is also used for  
21 the purpose of inducing delivery in the event of a second- or third-trimester  
22 loss.

1           17. For gestation of up to 70 days, the standard of care of medication  
2 abortion with the two-drug regimen involves one dose of mifepristone and one  
3 dose of misoprostol. A patient first takes mifepristone, which terminates a  
4 pregnancy by blocking the hormone progesterone. Progesterone is necessary for  
5 the maintenance of a pregnancy. Between 24 and 48 hours later, the patient  
6 takes misoprostol, which causes cramping and bleeding to expel the contents of  
7 the uterus.

8           18. The use of mifepristone in combination with misoprostol is widely  
9 considered in the field of obstetrics and gynecology to be the gold standard for  
10 medical management of miscarriages and medication abortions. That has been  
11 the case since the early 2000s, when peer-reviewed studies demonstrated that  
12 the use of mifepristone and misoprostol together is both safer and more  
13 effective than the use of misoprostol alone.

14           19. The prescription and use of mifepristone with misoprostol is the  
15 standard of care for miscarriage management and medication abortion in the  
16 State of Oregon and has been since 2018 after the publication by Schreiber.<sup>1</sup>  
17 Since the FDA approval of mifepristone, all medication abortions that I have  
18 provided have been via the two-drug regimen of mifepristone and misoprostol.

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20  
21           <sup>1</sup> Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart  
22 KT. Mifepristone Pretreatment for the Medical Management of Early Pregnancy  
Loss. N Engl J Med. 2018 Jun 7;378(23):2161-2170.



1           20. Although misoprostol can be prescribed alone for miscarriage  
2 management or medication abortions, it has a lower success rate and requires  
3 higher and more frequent doses, with increased undesirable patient side effects,  
4 including nausea, cramping, bleeding, and flu-like symptoms.

5           21. Mifepristone is one of a small number of medications that the FDA  
6 subjects to a Risk Evaluation and Mitigation Strategy (REMS). The REMS  
7 impose restrictions on how a drug may be prescribed and used.

8           22. REMS are typically applied to inherently dangerous drugs, such as  
9 opioids.

10          23. Mifepristone, however, is extremely safe. In fact, the medical  
11 literature contains a vast number of high quality, peer reviewed research papers  
12 that document the safety and efficacy of the use of mifepristone. For example, a  
13 2022 study conducted by Schummers *et al.* documented 84,000 patient  
14 experiences with mifepristone/misoprostol abortion with exceptionally low  
15 rates of complications.<sup>2</sup> That study showed a 0.04 percent incidence of severe  
16 complications (hospitalization, sepsis, transfusion, or surgery).

17          24. I have also personally studied its safety and efficacy in the clinical  
18 trial that led to FDA's approval. The FDA's own publications on mifepristone

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19  
20           <sup>2</sup> Schummers L, Darling EK, Dunn S, McGrail K, Gayowsky A, Law MR,  
21 Laba TL, Kaczorowski J, Norman WV. Abortion Safety and Use with Normally  
22 Prescribed Mifepristone in Canada. N Engl J Med. 2022 Jan 6;386(1):57-67.

1 show that the drug is safe and effective, demonstrating no scientific basis for  
2 subjecting the drug to REMS restrictions.

3 25. The REMS for mifepristone require certifications for prescribers  
4 (such as providers) and pharmacies. It further requires that mifepristone be  
5 dispensed by or under the supervision of a certified prescriber, or by certified  
6 pharmacies for prescriptions issued by certified prescribers. The REMS also  
7 require the use of certification forms for the pharmacy and prescriber (or  
8 provider), as well as a patient-agreement form.

9 26. The mifepristone REMS does not enhance patient safety, because  
10 its requirements are redundant with what healthcare providers already do. For  
11 example, the provider certification form requires the provider to certify that  
12 they can accurately date a pregnancy, diagnose an ectopic pregnancy, and treat  
13 complications that may arise or refer to someone who could. But medical  
14 providers qualified to provide a medication abortion are necessarily trained in  
15 pregnancy dating, ectopic risk factors, and care coordination.

16 27. The Patient Agreement Forms required by the REMS also can  
17 cause patient confusion, concern, and emotional distress. For example, the form  
18 requires the patient to declare they “have decided to take mifepristone and  
19 misoprostol *to end my pregnancy.*” But mifepristone is not just used for  
20 medication abortion; it is also the standard of care for medically managing  
21 miscarriage. Second, the form requires the patient to declare they “will take the  
22 misoprostol tablets 24 to 48 hours after I take mifepristone.” But emerging

1 medical evidence suggests that misoprostol may sometimes be appropriately  
2 taken fewer than 24 hours after taking mifepristone, and sometimes even  
3 concurrently. Thus, for those patients whose doctors direct them to take  
4 misoprostol fewer than 24 hours after mifepristone, the Patient Agreement  
5 Form is contrary to their doctor's advice and may lead to confusion. And, as I  
6 noted above, the Patient Agreement Form can also cause additional patient  
7 stress as the form causes some to worry that the medication is actually more  
8 dangerous than it is. The Patient Agreement Form makes counseling more  
9 difficult, especially in circumstances requiring a translator.

10 28. In my practice, I have seen patients for miscarriage and abortion  
11 care through my services at OHSU, Planned Parenthood, and the Lilith Clinic.  
12 When patients in early pregnancy contact those clinics seeking abortion care,  
13 their staff schedules them for either an in-person or telehealth consultation. For  
14 my consultations, I begin each visit by reviewing the patient's medical history  
15 and symptoms to determine what types of abortions for which the patient is  
16 eligible. I then discuss with the patient the risks, benefits, and alternatives for  
17 each kind of abortion care for which they are eligible. Lastly, I answer any  
18 questions they have so that they are able to make an informed decision.

19 29. If they are eligible for, and choose, a medication abortion, we  
20 proceed with the visit for that care.

21 30. I discuss the medication abortion process and discuss the Patient  
22 Agreement Form with the patient. After the patient answers my questions, I ask

1 whether they consent to a medication abortion. If they do, I confirm that  
2 consent in their medical record.

3 31. I then go over the instructions for how and when to take their  
4 medications, what the follow-up process is, what they should do if they  
5 experience any of the (very rare) serious complications associated with  
6 mifepristone or misoprostol, and I answer any additional questions they may  
7 have.

8 32. I am also required by the REMS to review and have the patient  
9 sign the Patient Agreement Form. The Patient Agreement Form is duplicative  
10 of the information contained in the FDA's Medication Guide, which is  
11 dispensed to the patient with the medication.

12 33. I also prescribe mifepristone (with misoprostol) to patients who are  
13 experiencing a miscarriage. Under the REMS, I am required to sign the same  
14 Patient Agreement Form as I am for patients receiving mifepristone for a  
15 medication abortion. That is confusing and often distressing for patients. I have  
16 had patients, who were already undergoing the traumatizing experience of a  
17 miscarriage, become upset at having to sign a form about medication abortion  
18 despite my explaining the regulatory requirements.

19 34. As with any other medical procedure, I discuss risks and benefits,  
20 alternatives, explain the treatment, and obtain informed consent for the  
21 prescription of mifepristone for miscarriage management or medication  
22 abortion. The Patient Agreement Form is duplicative of that counseling.

1           35. A frequent response from patients when we review the Patient  
2 Agreement Form is a look of concern on their face. Some expressed concern,  
3 assuming that the additional process was because mifepristone was inherently  
4 risky. I frequently need to explain to patients that it is an FDA-required process,  
5 and that the medical literature is replete with documentation of mifepristone's  
6 safety.

7           36. I am not aware of any other similar medication that requires these  
8 additional, duplicative, and onerous hurdles to receiving a prescription. Based  
9 on my experience, professional judgment, and the best available medical  
10 science, mifepristone is significantly safer than medications like Tylenol,  
11 Viagra, and penicillin, none of which have any REMS restrictions. More people  
12 die annually from those medications in the United States than from using  
13 mifepristone, yet none of those medications require patients to sign a specific  
14 consent form or undergo the counseling required by the mifepristone REMS.

15           37. I am not aware of any one of my several thousands of medication  
16 abortion patients experiencing a serious adverse reaction or death caused by  
17 mifepristone. It is among the safest drugs I have ever prescribed.

18 //

19 //

20 //

21 //

22 //








# Declaration of Dr. Mark Nichols

Final Audit Report

2023-02-22

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# EXHIBIT A



1

**CURRICULUM VITAE  
OREGON HEALTH & SCIENCE UNIVERSITY**

<b>NAME</b>	<b>Mark D. Nichols, MD</b>	<b>DATE</b>	February 22, 2023
<b>Academic Rank:</b>	<b>Emeritus Professor</b>		
<b>Department/Division:</b>	<b>Obstetrics and Gynecology</b>		
<b>Professional Address:</b>	<b>3181 SW Sam Jackson Park Road - UHN 50</b>		
<b>E-Mail Address:</b>	<b>nicholsm@ohsu.edu</b>		

**I. EDUCATION**

**Undergraduate and Graduate (Include Year, Degree, and Institution):**

1975 Bachelor of Science in Biological Sciences, University of California, Davis

**Postgraduate (Include Year, Degree, and Institution):**

1979 Doctor of Medicine, University of California, Davis

1979-1983 Internship and Residency  
Department of Obstetrics and Gynecology  
Oregon Health Sciences University

1990 Research Fellow  
Margaret Pyke Center, Middlesex Hospital  
University College, London, England  
(January - July)

July, 1996 Advanced Cardiac Life Support Provider Course  
American Heart Association  
Portland OR (Recertified in biannually, last in April, 2020)

**Certification (Include Board, Number, Date, and Recertification):**

American Board of Obstetrics and Gynecology, December 1985

Elected Fellow American College of Obstetrics and Gynecology, September 1986

**Licenses (Include State, Date, Status, Number, and Renewal Date):**

April 11, 1981 State of Oregon, License No. 12638, biannually renewed,  
Sept. 2010 Zambia, Temporary Medical License

**II. PROFESSIONAL EXPERIENCE**

**Academic (Include Year, Position, and Institution):**

1983 - 1993 Assistant Professor, Oregon Health Sciences University  
1993 - 2003 Associate Professor, Oregon Health & Science University  
2003 - 2022 Professor, Oregon Health & Science University  
2022 - present Emeritus Professor, Oregon Health & Science University

**Administrative (Include Year, Position, and Institution):**

1983 - 1995 Assistant Director, Residency Training Program, Oregon Health Sciences University,  
Department of Obstetrics and Gynecology  
1988 - 2013 Chief, Division of General Gynecology and Obstetrics, Department of Obstetrics and Gynecology,  
Oregon Health & Science University, Portland OR  
2001 - 2010 Director, Family Planning Fellowship, Oregon Health & Science University, Portland OR

2

2010 - 2013 Co- Director, Family Planning Fellowship, Oregon Health & Science University, Portland OR  
 2013 – present Director Emeritus, Family Planning Fellowship, Oregon Health & Science University, Portland OR

**Other (Include Year, Position, and Institution):**

1994 Interim Medical Director, Planned Parenthood Columbia Willamette Affiliate  
 1994 - 2011 Medical Director, Planned Parenthood Columbia Willamette Affiliate  
 2011 - 2013 Co-Medical Director, Planned Parenthood Columbia Willamette Affiliate  
 1997 - 2001 Family Planning Consultant, Oregon Health Division  
 2022 Consultant, Medecins Sans Frontieres, Safe Abortion Care

**International Work**

2010 Consultant, Population Services International, Zambia  
 2010 Member, Surgical Team mission to Gimbie Hospital, Ethiopia  
 2012 Consultant, Population Services International, Nigeria  
 2014 Consultant, Population Services International, Tanzania  
 2014 Visiting Professor, Mekelle University, Ethiopia  
 2015 Obstetrician, Medecins Sans Frontieres, South Sudan  
 2015 Consultant, Laos Nutrition Institute, Vientiane, Laos  
 2016 Visiting Professor, Mekelle University, Ethiopia  
 2017 Obstetrician, Medecins Sans Frontieres, South Sudan  
 2018 Consultant, Population Services International, Vietnam

**III. SCHOLARSHIP**

**Area(s) of Research/Scholarly Interest:**

Family planning with particular interest in surgical and medical abortion, emergency contraception, hormonal contraception, and training fellows, residents and medical students in family planning.

**Grants and Contracts:**

1. R W Johnson Pharmaceutical, "A Double Blind Placebo Controlled Safety and Efficacy Study of Antocin™ for the Prolongation of Gestation," November 1994 - July 1997, \$138,654. PI: Jeff Jensen, MD, Sub PI: Mark Nichols, MD
2. The Population Council, Inc., RU-486, "Evaluation of the Efficacy, Safety and Acceptability of Mifepristone and Misoprostol in Inducing Abortion in Pregnant Women with Amenorrhea of up to 63 Days," November 1994 - December 1995 - \$209,800. PI: Mark Nichols, MD
3. Wyeth-Ayerst Laboratories and University Hospital Consortium, "Norplant Observational Cohort," June 1995 - June 2003, \$275,000. PI: Mark Nichols, MD
4. Wyeth-Ayerst Laboratories, "A Multi center, Open-Label, Randomized, Comparative Study to Evaluate the Effects of Alesse™ and Loestrin FE 1/20® on Clinical and Biomedical Measures of Androgenicity," November 1996 - June 1997, \$16,920. PI: Mark Nichols, MD
5. Parke-Davis, "A Randomized, Double Blind, Active-Controlled, Parallel Group, Multi-center Study Assessing Menstrual Cycle Control and Ovulation Suppression Associated with Vaginal Administration of Five Dose Combinations of Norethindrone Acetate and Ethinyl Estradiol," December 1996 - March 1997, \$86,689. PI: Leon Speroff, MD, Sub PI: Mark Nichols, MD

3

6. Pharmacia & Upjohn, "Cyclo Provera™ Contraceptive Injection: A Comparative Study of Safety, Patient Acceptability and Efficacy to Ortho-Novum® 7/7/7, 28 Tablets," June 1997 - June 1999, \$92,556. PI: Mark Nichols
7. Organon, "An Open Label, Multi center, Randomized, Comparative Safety, Efficacy, Cycle Control, and Quality of Life Study of CTR 25, Alesse™, and Ortho Tri-Cyclen®," April 1998 - July 1999, \$76,310. PI: Kenneth Burry, MD, Sub PI: Mark Nichols, MD
8. John Hopkins University, "Comparing Acceptability of Manual vs Electrical Vacuum Aspiration for First Trimester Induced Abortion," \$37,310. June 2000 – July 2001. PI: Mark Nichols, MD
9. Pharmacia Co. "Phase III Study of DMPA Injection (DMPA-SC) in Women with Endometriosis in the US and Canada" \$42,480. January 2000 - January 2001. PI: Mark Nichols
10. Galen Holdings "A Multi-center, Randomized Controlled Double-Blind Study to Determine Efficacy in the Relief of Hot Flushes in Women Receiving Oral Estradiol" \$23,527. Sept. 2001 – Aug. 2002. PI: Leon Speroff, MD, Sub-PI: Mark Nichols, MD
11. Organon-Thebes "A Multinational, Multi-center, Randomized Controlled Trial, to Assess the Endometrial Histological Profile Following Treatment with Tibolone (ORG OD14) Versus Conjugated Estrogen (CE) Plus Medroxyprogesterone Acetate (MPA) in Postmenopausal Women" \$138,000. PI: Jeffrey Jensen, MD, Sub PI: Mark Nichols, MD
12. Pfizer Care "A Randomized, Double Blind, Multi-Center, 24 Week Study to Assess Cumulative Amenorrhea in Postmenopausal Women Taking Femhrt® and Prempro®". \$37,275. PI: Leon Speroff, MD, Sub-PI: Mark Nichols, MD
13. Buffett Foundation Grant. "Intrauterine Lidocaine Infusion for Pain Management in First Trimester Abortions" \$48,000. June 2002 – June 2003 PI: Alison Edelman, MD Sub PI: Mark Nichols, MD
14. Buffett Foundation Grant. "Continuous Oral Contraceptive Pills: Are Bleeding Patterns Dependent on the Hormone Chosen?" \$51,000. PI: Alison Edelman, MD Sub PI: Mark Nichols, MD

#### **Publications/Creative Work:**

##### Peer-reviewed

1. **Nichols, M.** Diagnosing Breast Disease, *West. J. Med.*, 148:324, 1988.
2. Novy MJ, Haymond J, **Nichols M.** Shirodkar Cerclage in a Multifactorial Approach to the Patient with Advanced Cervical Changes, *AJOG*, 162:1412-20, 1990.
3. **Nichols MD.** Review of Vulvar Ulcers, *Postgraduate Obstet. Gynecol.*, 11(No. 7):1991.
4. **Nichols M,** Robinson GER, Bounds W, Johnson J, Upward E, Newman B, Guillebaud J. Effect of Four Combined Oral Contraceptives on Blood Pressure in the Pill-Free Interval, *Contraception*, 47:367-76, 1993.
5. Thurmond A, Weinstein A, Jones M, Jensen J, **Nichols M.** Localization of Contraceptive Implant Capsules for Removal, *Radiology*, 193:580-581, 1994.
6. Carp H, Jayaram A, Vadhera R, **Nichols M,** Morton M. Epidural Anesthesia for Cesarean Delivery and Vaginal

Birth After Maternal Fontan Repair: Report of Two Cases, *Anesth Analg*, 78:1190-2, 1994.

7. **Nichols M.** Curriculum Change in an OB/GYN Residency Program and It's Impact on Pregnancy in Residency, *AJOG*, 170:1658-65, 1994.
8. Winikoff B, Ellertson C, Elul B, Sivin I; for the Mifepristone Clinical Trials Group. Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol. Results of Large Multi center Trial in the United States, *Arch Fam Med*, 7:360-6, 1998. (Member of the Mifepristone Clinical Trials Group)
9. Spitz IM, Bardin CW, Benton L, Robbins A. Early Pregnancy Termination with Mifepristone and Misoprostol in the United States, *New Eng J Med*, 338:1241-7, 1998. (Cited as Principal Investigator)
10. Jensen JT, Astley SJ, Morgan E, **Nichols MD.** Outcomes of Suction Curettage and Mifepristone Abortion in the United States, *Contraception*, 59(3):153-9, 1999.
11. Kaunitz AM, Garceau RJ, Cormie MA, Lunelle Study Group (Member). Comparative Safety, Efficacy and Cycle Control of LUNELLE Monthly Contraceptive Injection (Medroxyprogesterone Acetate and Estradiol Cypionate Injectable Suspension) and Ortho-Novum 7/7/7 Oral Contraceptive (Norethindrone/Ethinyl Estradiol Triphasic), *Contraception*, 60:179-187, 1999.
12. Thorneycroft IH, Stanczyk FZ, Bradshaw KD, Ballagh SA, **Nichols M**, Weber ME. Effect of Low-dose Oral Contraceptives on Androgenic Markers and Acne, *Contraception*, 60:255-62, 1999.
13. Paul M, Schaff E, **Nichols M.** The Roles of Clinical Assessment, Human Chorionic Gonadotropin Assays, and Ultrasonography in Medical Abortion Practice, *Am J Obstet Gynecol*, 183(2):S34-S43, 2000.
14. Borgatta L, Burnhill M, Haskell S, **Nichols M**, Leonhardt K. Instituting Medical Abortion Services: Changes in Outcome and Acceptability Related to Provider Experience, *JAMWA*, 55:173-6, 2000.
15. Westhoff C, Dasmahapatra R, Winikoff B, Clarke S, and the Mifepristone Clinical Trials Group. Predictors of analgesia use during supervised medical abortion. *Contraception* 2000;61:225-229 (Member of the Mifepristone Clinical Trials Group)
16. Bird ST, Harvery SM, **Nichols M.** Comparing the Acceptability of Manual Vacuum Aspiration and Electric Vacuum Aspiration as Methods of Early Abortion. *JAMWA* 56: 124-126;2001
17. Edelman AT, **Nichols MD**, Jensen J. Comparison of pain and time of procedures with two first-trimester abortion techniques performed by residents and faculty *Am J Obstet Gynecol* 184:1564-7;2001
18. **Nichols M**, Edelman A. RU 486 for Primary Care Providers. *Primary Care Reports* , 7:89-95;2001
19. Phair N, Jensen J, **Nichols M.** Paracervical block and elective abortion: The effect of waiting between injection and procedure pain. *Am J. Obstet. Gynecol.* 186:1304-7;2002
20. **Nichols M**, Morgan E, Jensen J. Comparing bimanual pelvic examination to ultrasound measurements for the assessment of gestational age in the first trimester of pregnancy. *Journal Repro Med* 50:825-8;2002
21. Kwiecien M, Edelman A, **Nichols MD**, Jensen JT. Bleeding patterns and patient acceptability of standard or continuous dosing regimens of a low dose oral contraceptive: a randomized trial. *Contraception* 67:9-13;2003
22. Edelman A, Jensen J, Nelson E, and **Nichols M.** Cannula fracture in first trimester abortion: a case report and

survey of National Abortion Federation providers. *Contraception* 67:49-51;2003

23. Bird ST, Harvey SM, Beckman LJ, **Nichols MD**, Rogers K, and Blumenthal PD. Similarities in Women's Perceptions and Acceptability of Manual Vacuum Aspiration and Electric Vacuum Aspiration for First Trimester Abortion. *Contraception* 67:207-212;2003.
24. Picardo CM, **Nichols MD**, Edelman AE, Jensen JT. Attitudes and information sources of the risks and benefits of oral contraception. *JAMWA* 58:112-116;2003
25. Edelman A.B., Jensen J.T., Lee D.M., Nichols M.D. Successful medical abortion of a pregnancy within a non-communicating rudimentary uterine horn. *AJOG* 189:886-7;2003
26. Emmons S, Adams KE, Cain JM, **Nichols M.** The impact of perceived gender bias on obstetric and gynecology skills acquisition by third year medical students. *Academic Medicine*, 79:1-7;2004
27. Edelman A, **Nichols M**, Leclair C, Astley S, Shy K, and Jensen JT. Intrauterine Lidocaine Infusion for Pain Management in First-Trimester Abortions *Obstet. Gynecol.* 103:1267-127;2004
28. Smits AK, Clark EC, **Nichols MD**, Saultz JW. Factors Influencing Cessation of Maternity Care in Oregon. *Family Medicine* 36:87-92;2004
29. Cwiak CA, Edelman AB, Hatcher RA, Zieman M, **Nichols MD**, Jensen JT, Emmons SL, and Khan IM. Teaching contraception: An interactive presentation using *Managing Contraception*. *AJOG* 191:1788-92;2004
30. Harvey S M, **Nichols MD**. Development and Evaluation of the Abortion Attributes Questionnaire. *Journal of Social Issues*. 61:95-107;2005
31. Edelman A.B., Jensen J.T., Lee D.M., **Nichols M.D.**, Buckmaster J, Goetsch, M. Cervical preparation using laminaria with adjunctive buccal misoprostol prior to second trimester dilation and evacuation procedures: a randomized clinical trial, *AJOG* 194:425-30;2006
32. Emmons SL. Adams KE. **Nichols M.** Cain J. The impact of perceived gender bias on obstetrics and gynecology skills acquisition by third-year medical students. *Academic Medicine* 79:326-32;2004
33. Emmons SL. **Nichols M.** Schulkin J. James KE. Cain JM. The influence of physician gender on practice satisfaction among obstetrician gynecologists. *American Journal of Obstetrics & Gynecology*. 194:1728-38; 2006
34. Edelman AB. Gallo MF. Jensen JT. **Nichols MD**. Schulz KF. Grimes DA. Continuous or extended cycle vs. cyclic use of combined oral contraceptives for contraception. *Cochrane Database of Systematic Reviews*. (3):CD004695, 2005.
35. Edelman A.B., Jensen J.T., **Nichols M.D.** Continuous Oral Contraceptives: Are Bleeding Patterns Dependent on the Hormones Given? *Obstetrics & Gynecology* 107:657-65, 2006
36. Edelman, Alison MD, MPH; Nichols, **Mark D. MD**; Leclair, Catherine MD; Jensen, Jeffrey T. MD, MPH. Four Percent Intrauterine Lidocaine Infusion for Pain Management in First-Trimester Abortions. *Obstetrics & Gynecology* 107:269-275;2006.
37. Edelman A, M.F. Gallo MF, **Nichols MD**, Jensen JT, Schulz K, and Grimes DA. Continuous versus cyclic use of combined oral contraceptives for contraception: systematic Cochrane review of randomized controlled trials.

*Hum. Reprod.* 2006 21: 573-578.

38. **Nichols M**, Carter J, and Fylstra D. A comparative study of hysteroscopic sterilization performed in-office versus a hospital operating room. *Journal of Minimally Invasive Gynecology* 13:447-50, 2006.
39. Edelman A, Lew R, Cwiak C, **Nichols M**, Jensen J. Acceptability of contraceptive-induced amenorrhea in an racially diverse group of U.S. women. *Contraception* 2007;75:450-453.
40. Kaskowitz A., Carlson N., **Nichols M.**, Edelman A., Jensen J. Online Availability of Hormonal Contraceptives Without a Health Care Examination: Effect of Knowledge and Health Care Screening. *Contraception.* 76:273-7;2007
41. Munks EB, Edelman AB, Jensen JT, **Nichols MD**, Burry K and Patton P. IVF Patients' Attitudes Toward Multifetal Pregnancy Reduction. *Journal of Repro Med* 52:635;2007
42. Bednarek PH, **Nichols MD**, Carlson N, Edelman AB, Creinin MD, Truitt S, Jensen JT. Effect of "Observed Start" versus traditional "Sunday Start" on hormonal contraceptive continuation rates after medical abortion. *Contraception* 78:26-30,2008
43. Kaneshiro B, Jensen JT, Carlson N, **Nichols M**, Edelman A. The Association of Body Mass Index and Unintended Pregnancy in the US: Results from Cycle 6 of the National Survey of Family Growth. *Contraception* 77(4):234-8, 2008 Apr
44. Singh RH, Ghanem KG, Burke AE, **Nichols MD**, Rogers K, Blumenthal PD. Predictors and perception of pain in women undergoing first trimester surgical abortion. *Contraception* 78(2):155-161;2008
45. Michelle M. Isley, Alison Edelman, Bliss Kaneshiro, Dawn Peters, **Mark D. Nichols**, and Jeffrey T. Jensen. Sex education and contraceptive use at coital debut in the U.S.: Results from cycle 6 of the National Survey of Family Growth. Accepted in *JAMA*
46. Kaneshiro B. Jensen JT. Carlson NE. Harvey SM. **Nichols MD**. Edelman AB. Body mass index and sexual behavior. *Obstetrics & Gynecology.* 112(3):586-92, 2008 Sep.
47. Stanek AM, Bednarek PH, **Nichols MD**, Jensen JT, Edelman AB. Barriers associated with the failure to return for intrauterine device insertion following first-trimester abortion. *Contraception.* 79:216-20, 2009
48. Kraemer DF, Yend, P, **Nichols, M**. An economic comparison of female sterilization of hysteroscopic tubal occlusion with laparoscopic bilateral tubal ligation. *Contraception* 80: 254–260, 2009
49. Renner RM. Jensen JT. Nichols MD. Edelman A. Pain control in first trimester surgical abortion. *Cochrane Database of Systematic Reviews.* (2):CD006712, 2009.
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51. Renner RM. Jensen JT. **Nichols MD**. Edelman AB Pain control in first-trimester surgical abortion: a systematic review of randomized controlled trials. *Contraception.* 81(5):372-88, 2010 May.
52. Isley M, Edelman A., Kaneshiro B., Peters, D. **Nichols, M**, Jensen, JT. Sex education and contraceptive use at coital debut in the United States: results from Cycle 6 of the National Survey of Family Growth. *Contraception.*

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53. Kaneshiro B, Bednarek P, Isley M, Jensen J, **Nichols M**, Edelman A. Blood loss at the time of first-trimester surgical abortion in anticoagulated women. *Contraception* 2011; 83:431-435.
54. Renner RM, **Nichols M**, Jensen JT, Hong L, Edelman AB. Paracervical block for pain control in first-trimester surgical abortion: a randomized controlled trial. *Obstet Gynecol* 2012; 119: 1030-1037.
55. Kaneshiro B, Edelman AB, Carlson N, **Nichols M**, Jensen JT. A randomized controlled trial of subantimicrobial doxycycline to prevent unscheduled bleeding with continuous oral contraceptive pill use. *Contraception*.2012; 85: 351-358.
56. Isley MM, Jensen JT, **Nichols MD**, Lehman A, Bednarek P, Edelman A. Intrauterine lidocaine infusion for pain management during outpatient transcervical tubal sterilization: a randomized controlled trial. *Contraception* 2012; 85: 275-281.
57. Kaneshiro B, Edelman A, Carlson N, **Nichols M**, Jensen J. Unscheduled bleeding with continuous oral contraceptive pills: a comparison of progestin dose. *Contraception accepted 2011, available epub*
58. Bayer LL; Jensen JT; Li H; **Nichols MD**; Bednarek PH. Adolescent experience with intrauterine device insertion and use: a retrospective cohort study. *Contraception*. 86(5):443-51, 2012 Nov.
59. Micks EA; Edelman AB; Renner RM; Fu R; Lambert WE; Bednarek PH; **Nichols MD**; Beckley EH; Jensen JT. Hydrocodone–Acetaminophen for Pain Control in First-Trimester Surgical Abortion: A Randomized Controlled Trial. *Obstetrics & Gynecology*. 120(5):1060-9, 2012 Nov.
60. Goldthwaite LM; Baldwin MK; Page J; Micks EA; **Nichols MD**; Edelman AB; Bednarek PH. Comparison of interventions for pain control with tenaculum placement: a randomized clinical trial. *Contraception*. 89(3):229-33, 2014 Mar.
61. Krashin JW; Edelman AB; **Nichols MD**; Allen AJ; Caughey AB; Rodriguez MI. Prohibiting consent: what are the costs of denying permanent contraception concurrent with abortion care?. *American Journal of Obstetrics & Gynecology*. 211(1):76.e1-76.e10, 2014 Jul.
62. Bayer LL; Edelman AB; Fu R; Lambert WE; **Nichols MD**; Bednarek PH; Miller K; Jensen JT. An Evaluation of Oral Midazolam for Anxiety and Pain in First-Trimester Surgical Abortion: A Randomized Controlled Trial. *Obstetrics & Gynecology*. 126(1):37-46, 2015 Jul.
63. Micks E, Edelman A, Botha R, Bednarek P, **Nichols M**, Jensen J. The effect of sevoflurane on interventions for blood loss during dilation and evacuation procedures at 18–24 weeks of gestation: a randomized controlled trial. *Contraception* 91 (2015) 488–494
64. Baldwin MK, Edelman AB, Lim JY, **Nichols MD**, Bednarek, PH,, Jensen JT. Intrauterine device placement at 3 versus 6 weeks postpartum: a randomized trial. *Contraception* 93 (2016) 356–363
65. Renner R-M, Edelman AB, **Nichols MD**, Jensen JT, Lim JY, Bednarek PH Refining paracervical block techniques for pain control in first trimester surgical abortion: a randomized controlled noninferiority trial. *Contraception* 94 (2016) 461–466
66. Patil E, Darney B, Orme-Evans K, Beckley E, Bergander L, **Nichols M**, Bednarek PH. Aspiration Abortion With Immediate Intrauterine Device Insertion: Comparing Outcomes of Advanced Practice Clinicians and Physicians.



*Journal of Midwifery & Women's Health. 61(3):325-330, March 2016*

67. Bayer LL, Edelman AB, Fu R, Lambert WE, **Nichols MD**, Bednarek PH, Miller K, Jensen JT. An Evaluation of Oral Midazolam for Anxiety and Pain in First-Trimester Surgical Abortion. A Randomized Controlled Trial. *Obstet Gynecol* 2015;126:37–46

#### Non-peer-reviewed

1. Nichols MD. Formal Discussant. An Obstetric and Gynecologic Clerkship's Influence on a Medical Community, *Am J Obstet Gynecol*, 176:1363-8, 1997.
2. Nichols, MD. Formal Discussant. Real-time Ultrasonographically Guided Removal of Nonpalpable and Intramuscular Norplant Capsules, *Am J Obstet Gynecol*, 178:1185-93, 1998.
3. Nichols, MD. Formal Discussant. Cytologic evaluation of non-bloody breast cyst fluid. *Am J Obstet Gynecol*, *Am J Obstet Gynecol*, 182:1300-5, 2000
4. Nichols, MD. Letter to the Editor, "Fewer Abortions would be needed". *Oregonian*, June 15, 2001
5. Nichols, MD. Methotrexate for management of a pregnancy in a non-communicating uterine horn. Letter to the editor. *Journal Repro Med* 50:878-9;2002
6. Nichols, MD. Clinical Trials Report, *Current Women's Health Reports*, 2:407-408;2002
7. Reeves MF; Blumenthal PD; Jones RK; **Nichols MD**; Saporta VA. New research at the 2014 National Abortion Federation Annual Meeting: continuously improving abortion care. *Contraception. 89(5):339-40, 2014 May.*
8. Reeves MF; Blumenthal PD; Jones RK; **Nichols MD**; Saporta VA. New research at the 2015 National Abortion Federation Annual Meeting: putting research into practice. *Contraception. 91(5):359, 2015 May.*
9. Darney P; Creinin MD; **Nichols M**; Gilliam M; Westhoff CL; Tenth anniversary of the Society for Family Planning. *Contraception. 92(4):279-81, 2015 Oct.*

#### Publications (submitted)

#### Chapters

1. Nichols M. "Faculty Ownership". In: *Teaching and Evaluating Clinical Skills*, 1995, APGO.
2. Nichols M, Halvorson-Boyd G, Goldstein R, Gevirtz D and Healow D. "Pain Management" in *Management of Unintended and Abnormal Pregnancy*. Wiley –Blackwell, 2009

#### Abstracts

1. Thulin PC, Carter JH, Nichols MD, Kurth M, Nutt JG. Menstrual-cycle Related Changes in Parkinson's Disease, *Neurology*, 46:A376, 1996.



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2. Fossum GT, Thomas M, Wise R, Nichols M, Sinofsky F, Pasquale S. Preliminary Evaluation of a New Instrument Design for the Removal of Norplant Capsules.
3. Bird ST, Harvey SM, Nichols MD. Women's Acceptability of Manual Vacuum Aspiration (MVA: An Exploratory Study of Abortion Patients in Portland, Oregon.
4. Romm J, Nichols M. The Men's Group: Discussion Group for Male OB/GYN Residents, International Society of Psychosomatic Obstetrics and Gynecology, June 1998, Washington DC.
5. Stanczyk FZ, Bradshaw KD, Ballagh BA, Nichols MD, Thorneycroft, LH. Effect of Oral Contraceptive Progestins on Production of Ovarian, Adrenal and Peripheral Androgens, European Society of Contraception, June 1998, Prague.
6. Sheryl Thornbird PhD, Marie Harvey DrPH, Linda Beckman, PhD, Mark Nichols, MD, Paul Blumenthal. MD. Men's involvement in abortion: Perceptions of women having abortions in three U.S. cities Population, Family Planning, and Reproductive Health section of the 130th Annual APHA Meeting, Philadelphia, PA November, 2002.
7. Singh RH, Nichols MD, Rogers K, Ghanem KG, & Blumenthal Pd. Subjective predictors of pain in women undergoing electrical vacuum aspiration (eva) versus manual vacuum aspiration (mva) for first trimester abortion. Assoc. of Reproductive Health Professionals Annual meeting, Tampa FL, Sept. 2005
8. Edelman A, Nichols M, Leclair C, & Jensen JT. 4% intrauterine lidocaine infusion for pain management in first trimester abortions. Assoc. of Reproductive Health Professionals Annual meeting, Tampa FL, Sept. 2005.
9. Drath E, Nichols M, & Edelman A. Ultrasound, Twin Gestation, and Abortion Decision Making: Patients and Providers. NASPOG Annual Scientific Meeting, February, 2006, Hawaii
10. Bednarek P, Nichols M, Edelman A, Jensen JT, Truitt S, Creinin MD. Effect of observed start compared with Sunday start on contraceptive continuation after medical abortion. *Obstet Gynecol* 2007, supp 57S.

#### Audio Presentations

1. "RU-486," Audio-Digest Obstetrics and Gynecology, Vol. 41, No. 8, April 19, 1994
2. "Family Planning/STD Case Consultation," Center for Health Training, June 7, 1999
3. "Legal and Medical Implications of the Federal Abortion Ban" Podcast from Lewis & Clark Law School, Portland, OR Jan. 2006

#### Posters

1. Nichols MD, Kirk EP. Resident Retreat: A Stress Reducer and Morale Booster, CREOG and APGO Meeting, March 1991, Orlando, FL
2. Thomas L, Nichols MD. Ultrasound Evaluation of the Post Mifepristone Abortion Patient, Pacific Coast Obstetrical and Gynecological Society, Sunriver OR, 1996
3. Edelman A, Nichols MD. Comparison of Resident and Faculty Performed Abortions using Two Different Abortion Techniques, District VIII Meeting, American College of Obstetricians and Gynecologists, Anchorage AK, August 2000

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4. Edelman A, Nichols MD. Comparison of Resident and Faculty Performed Abortions using Two Different Abortion Techniques, District VIII Meeting, American College of Obstetricians and Gynecologists, Anchorage AK, August 2000.
5. Phair N, Jensen J, Nichols M. Paracervical block and elective abortion: The effect of waiting between injection and procedure pain, PCOGS Annual meeting, Ashland OR, October, 2001. Received award as best poster of the meeting.
6. Lew R, Edelman A, Cwiak C, Jensen J, Nichols M. Acceptability of Contraceptive-Induced Amenorrhea in American Women, ACOG Annual Clinical Meeting, San Francisco, May 2005.
7. Koontz, Edelman A, Jensen J, Nichols M. Continuous Oral Contraceptives: Are Bleeding Patterns Dependent on the Hormones Given? ACOG Annual Clinical Meeting, San Francisco, May 2005.
8. Paula Bednarek, MD, Mark Nichols, MD, Alison Edelman, MD, MPH, Jeffrey T. Jensen, MD, MPH, Sarah Truitt, MD, Mitchell D. Creinin, MD. Effect of "Observed Start" versus "Sunday Start" on hormonal contraception continuation after medical abortion. ACOG Annual Clinical Meeting, San Diego, May 2007

Invited Lectures, Conference Presentations or Professorships (since promotion to Associate Professor):

Local (Selected)

1. "IUD Review," Grand Rounds, Kaiser Sunnyside Hospital, Department of Obstetrics and Gynecology, January 1993.
2. "Breast Disease for the Gynecologist," Langley Memorial Lectures, Portland OR, February 1993.
3. "Second Trimester Abortion Technique," Grand Rounds, Bess Kaiser Hospital, Obstetrics and Gynecology Department, April 1993.
4. "RU-486," City Club of Portland, July 1994.
5. "Circumcision Review," Grand Rounds, OHSU, Department of Obstetrics and Gynecology, June 1995.
6. "Abortion" and "Breast Disease," OHSU, Nursing School Advanced Gynecology Course, October 1995.
7. "Emergency Management of Vaginal Bleeding," St. Vincent Hospital, January 1996.
8. "Trauma in Pregnancy," OHSU, Emergency Medicine Residents, September 1996.
9. "Contraception Review," OHSU, Internal Medicine Residents, January 1997.
10. "Management of Miscarriages," OHSU, Student Health Service, January 1997.
11. "Contraception and World Population," Portland State University Population Control Class, January 1997.
12. "Emergency contraception: Coca-Cola to Mifepristone," Grand Rounds, OHSU, Department of Obstetrics and Gynecology, April 1997.
13. "First Trimester Bleeding," OHSU, Emergency Medicine Residents, June 1997.

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14. "Approach to Dysfunctional Uterine Bleeding," Grand Rounds, OHSU, Internal Medicine Department, March 1998.
15. "Medical Abortion Review," Kaiser Grand Rounds, Clackamas OR, December 1998.
16. "Update on Emergency Contraception and Medical Abortion," Grand Rounds, OHSU, Department of Obstetrics and Gynecology, January 1999.
17. "Emergency Contraception," OHSU, School of Nursing, Graduate Program, January 1999.
18. "Emergency Contraception," Planned Parenthood, Columbia/Willamette Affiliate, Portland OR, March 1999.
19. "Emergency Contraception," Mt. Hood Medical Center, OB/GYN and Pediatrics Department Meeting, June 1999.
20. "Abnormal Uterine Bleeding," Grand Rounds, OHSU, Department of Obstetrics and Gynecology, July 1999.
21. "Medical Abortion Review," St. Vincent Medical Center Ob/Gyn Dept., Portland OR, October 1999.
22. Norplant/IUD Training, Clinicians from Lane, Linn, Josephine, Tillamook, Marion, Coos, Polk, Lincoln, Malheur, Douglas, Washington, Multnomah and Klamath Counties and Planned Parenthood, Portland OR, November 1999.
23. "Review of Emergency Contraception," Tuality Hospital, Hillsboro OR, March 2000.
24. "Wedge Issues of Choice," NARAL Leadership Training, Unitarian Church, Portland OR, April 2000.
25. "Emergency Contraception" Emanuel Hospital, Ob/Gyn Department, June 2000
26. "Emergency Contraception" Center for Women's Health, OHSU, September 2000
27. "Mifepristone: FDA Approval and Review," OHSU, Grand Rounds, Department of Obstetrics and Gynecology, October 2000.
28. "RU486," OB/GYN Department Educational Conference, Providence St. Vincent Medical Center, Portland OR, March 2001.
29. "Review of Emergency Contraception". Pediatric Department, Emanuel Hospital, Portland, OR, February, 2002
30. "Contraceptive Update: What's New?" OHSU, Grand Rounds, Department of Obstetrics and Gynecology, March 2002.
31. "Women seeking abortion care. Are they discriminated against?" Reed College VOX course, Portland, OR, March, 2002.
32. "Update in Contraception" Lorenzen Women's Physician Forum, Portland, OR, November 2002
33. "Update in Contraception" Grand Rounds, Good Samaritan Hospital, Portland, OR, February 2003
34. "Becoming an abortion provider" Reed Vox seminar, Reed College, Portland, OR, April, 2003

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35. "Planned Parenthood Update" SW Washington Medical Center, Ob/Gyn Department Grand Rounds, Vancouver, WA, June, 2003
36. "Update on Contraception", Student Health Center, OHSU, November 2003
37. "IUD Review", Legacy Hospital CNM Department, Portland, OR February 2004
38. "Oral Contraceptive Update", St. Vincent Medical Center, Resident teaching conference, Portland, OR, March 2004
39. "Essure device for female sterilization", SW Washington Med. Center, Ob/Gyn dept. Grand Rounds, Vancouver, WA, Jan. 2005
40. "Transcervical Female Sterilization", East Portland Rotary Club, Portland, OR Jan. 2005
41. "Legal and Medical Implications of the Federal Abortion Ban" Lewis & Clark Law School, Portland, OR Jan. 2006
42. "Pain Management of Gynecologic Procedures" Grand Rounds, OHSU Ob/Gyn department, Portland, OR Oct. 2008
43. "Management of Breech Presentation" Grand Rounds, OHSU Ob/Gyn department, Portland, OR Sept 2009
44. "Alternatives to Hysterectomy" Brown Bag Lecture, OHSU, Portland, OR October 2009
45. "Pain management for gynecologic procedures", Grand Rounds Dept of Anesthesiology, OHSU, September 2010.

#### Regional

1. "Norplant Review and Insertion Training," Washington Academy of Family Practice Review Course, Spokane WA, April 1993.
2. "Gynecology for the Primary Care Provider: Preventive Health Care," Primary Care Conference, Sunriver OR, June 1993.
3. "Contraception for Patients with Chronic Health Problems," Nurse Practitioners of Oregon, September 1995.
4. "RU-486 Review," Ashbury Memorial Lectureship, Guest Speaker, Corvallis OR, November 1995.
5. "Common Gynecologic Problems and the Internist," 3rd Annual Internal Medicine Review Course, April 1996.
6. "Contraceptive Update," Family Planning Conference, Eugene OR, September 1996.
7. "Gynecological Procedures," 28th Annual Family Practice Review, Portland OR, February 1997.
8. "Contraception," 28th Annual Family Practice Review, Portland OR, February 1997.
9. "Family Planning," Reproductive Health Conference 1997, Portland OR, March 1997.
10. "Elective Abortions: RU-486 and Methotrexate," Reproductive Health Conference, Portland OR, March 1997.

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11. "Medical Abortion," 5th Annual Oregon Section ACOG Update in Obstetrics, Gynecology, and Primary Care, Bend OR, April 1997.
12. "Hormonal Contraception for Females: Recommendations and Guidelines," Endocrine Conference, Ashland OR, August 1997.
13. "Emergency Contraception: From Coca-Cola to Mifepristone," 21st Annual Pacific NW Review of OB-GYN, Portland OR, October 1997.
14. "Office Gynecology," 29th Annual Family Practice Review, Portland OR, February 1998.
15. "IUD Insertion Technique," Roseburg OR, March 1998.
16. "Office Gynecology," 5th Annual Internal Medicine Review, Portland, April 1998.
17. "Contraceptive Overview," Planned Parenthood, Eugene OR, November 1998.
18. "Emergency Contraception," 30th Annual Family Practice Review, Portland OR, February 1999.
19. "Gynecologic Procedures," 30th Annual Family Practice Review, Portland OR, February 1999.
20. "Emergency Contraception," Oregon Section, ACOG 6th Annual Meeting, Sunriver OR, April 1999.
21. "Emergency Contraception: New Innovations," Center for Health Training, 28th Annual Clinical Update, Portland OR, April 1999.
22. "Emergency Contraception," Sacred Heart Medical Center, 1st Annual Primary Care Conference, Eugene OR, May 1999.
23. "Update in Contraception," Sacred Heart Medical Center, 1st Annual Primary Care Conference, Eugene OR, May 1999.
24. "Laparoscopic Tubal Ligation Techniques," 23rd Annual Pacific NW Review of OB-GYN, Portland OR, October 1999.
25. "Impact of Religious Hospital Mergers on Training Residents in Abortion Care." Toward Rational Living Conference, Portland OR, November 1999.
26. "Gynecology: Office Procedures," 31st Annual Family Practice Review, Portland, February 2000.
27. "RU486 in OB/GYN," Women's Health Care Symposium, Eugene OR, September 2000.
28. "Savvy About Sex," Martha Browning Bryant Memorial Lecture, Oregon Chapter of The American College of Nurse-Midwives, October 2000.
29. "Emergency Contraception," Institute of Women's Health and Integrative Medicine, October 2000.
30. "Update on Pap Smears" Family Practice OB Ski and Women's Health Conference, Bend OR, January 2001.
31. "Gynecological Skills Workshop", Family Practice OB Ski and Women's Health Conference, Bend OR, January

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2001.

32. "Gynecology: Office Procedures," 32nd Annual Family Practice Review, OHSU, February 2001.
33. "Dysfunctional Uterine Bleeding," 8th Annual Internal Medicine Review, April 2001.
34. "Sonohysterography or SIS (Saline Infusion Sonography)," 8th Annual Oregon ACOG Update in Obstetrics and Gynecology, Bend OR, April 2001.
35. "Where are we with RU-486" Oregon Nurses Association/Nurse Practitioners of Oregon, 24th Annual Meeting, Eugene, OR Sept. 2001
36. "Pharmacology of Oral Contraceptives", OHSU with 4 remote sites, Nurse Practitioner curriculum, Oct. 2001
37. "Laparoscopic Supracervical Hysterectomy: Making the Recovery Even Faster". 25th Annual Pacific Northwest Review Conference, Portland OR, November 2001
38. "Review of Emergency Contraception", Oregon Pharmacology Association, Nov. 2001
39. "Intrauterine contraception" Nurse Practitioner Training Course, Portland, OR, Jan. 2002
40. "What's new in contraception?" Montana section ACOG Annual Meeting, Big Sky, MT, Feb. 2002
41. "RU-486 in Ob/Gyn", Montana section ACOG Annual Meeting, Big Sky, MT, Feb. 2002
42. "Review of Emergency Contraception", Montana section ACOG Annual Meeting, Big Sky, MT, Feb. 2002
43. "What's New in Contraception", 33rd Annual Family Practice Review, Portland, February, 2002
44. "Gynecologic Procedures" 33rd Annual Family Practice Review, Portland, February, 2002
45. "Update on Contraception" Good Samaritan Hospital, Corvallis, OR, March 2002
46. "RU-486 in Ob/Gyn" Good Samaritan Hospital, Corvallis, OR, May, 2002
47. "Labor Inductions" OAFP Women's Health Conference, Bend, OR, Jan. 2003
48. "The new IUD" OAFP Women's Health Conference, Bend, OR, Jan. 2003
49. "Update in Contraception" Reproductive Health Conference, Portland, OR, March 2003
50. "IUD training" Reproductive Health Conference, Portland, OR, March 2003
51. "Essure Device for Tubal Sterilization" 10th Annual Oregon ACOG Update in Obstetrics and Gynecology, Bend OR, April 2003.
52. "Update on Contraception for the New Millenium" Women's Health Care Symposium, Eugene, OR, May 2003
53. "Trans-Cervical Sterilization: A review of the Essure device" 27th Annual Pacific NW Review of OB-GYN, Portland OR, October 2003.

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54. "Medical Abortion Review" National Abortion Federation Course, Portland, OR, October, 2003
55. "What's New in Contraception", 35th Annual Family Practice Review, Portland, February, 2004
56. "Gynecologic Procedures" 35th Annual Family Practice Review, Portland, February, 2004
57. "IUD Training" Center for Health Training, Portland, OR October, 2004
58. "Why Women Wait". Western Regional meeting of Medical Students for Choice, Portland, October, 2004
59. "MVA Training Sessions" Western Regional meeting of Medical Students for Choice, Portland, October, 2004
60. "Ultrasound in Medical Abortion" Sponsored by NAF , Portland, OR, November, 2004
61. "Gynecologic Procedures" 36th Annual Family Practice Review, Portland, February, 2005
62. "Contraceptive Update" 36th Annual Family Practice Review, Portland, February, 2005
63. "Alternatives to Hysterectomy" 36th Annual Family Practice Review, Portland, February, 2005
64. "Looking in the Future: New Contraceptive Methods" Reproductive Health Conference, Portland, OR, March 2005
65. "Shortage of Abortion Providers in the U.S." Students for Choice conference, Willamette University, Jan. 2006
66. "Gynecology Procedures" 37<sup>th</sup> Annual Family Practice Review, Portland, February, 2006
67. "Review of Medical Abortion" Pacific Northwest Review Course, Portland, OR October, 2006
68. "Implanon training" Sponsored by Implanon, Portland, OR March, 2007
69. "Review of Contraceptive Implants" Reproductive Health 2007, Portland, OR March 2007
70. "Management of Early Pregnancy Failure", Nurse Practitioners of Oregon annual meeting, Hood River, OR Oct. 2008
71. "Medical Abortion", Nurse Practitioners of Oregon annual meeting, Hood River, OR Oct. 2008
72. "Addressing the abortion provider shortage" Western regional meeting, Medical Students for Choice, Portland, OR, April 2009

#### National

1. "IUD Review," Grand Rounds, University of Maryland, Obstetrics and Gynecology Department, February 1993.
2. "IUD Review," Grand Rounds, Pennsylvania Hospital, Obstetrics and Gynecology Department, May 1993.
3. "IUD Review," Grand Rounds, Maricopa County, Obstetrics and Gynecology Department, June 1993.
4. "OB/GYN Review Course," Loma Linda University, Guest Faculty, Yosemite CA, April 1995.

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5. "Incorporating Abortion Training Into the Ob/Gyn Residency Curriculum," National Abortion Federation Conference, Baltimore MD, November 1998
6. "Second Trimester Abortion Technique" and "Abortion Providers Panel: Incorporating Abortion Care Into Your Practice," Medical Students for Choice, 6th Annual Meeting, Atlanta, GA, April 1999.
7. "Fine Needle Aspiration for the Evaluation of Breast Masses," National Medical Committee Planned Parenthood Federation of America, Dallas TX, Sept. 1999.
8. "Parenteral Estrogen and Progestin Contraceptive: a Review," Risk Management Seminar, National Abortion Federation, Denver CO, Sept. 1999.
9. "Faculty Models" National Abortion Federation Resident Training Workshop, New Orleans LA, February 2000.
10. "Building Support in Your Department & Negotiating the Contract: From a Residency Program Perspective," National Abortion Federation Resident Training Workshop, New Orleans LA, February 2000.
11. "Background/Historical Context," "Medications: Mifepristone, Misoprostol and Methotrexate," "Protocol," "Patient Management," National Abortion Federation & Planned Parenthood Federation of America "Mifepristone 2000," Pleasant Hill CA, March 2000.
12. "Required Training in Abortion" Training in Abortion: The Next Level, Washington DC, October 2000
13. "Family Planning Fellowships and Planned Parenthood", PPFA National Medical Committee, Washington DC, December, 2001
14. "Evidence Based Regimen for mifepristone abortions" National Abortion Federation Annual Meeting, San Jose, CA, April 2002
15. "Faculty Models" National Abortion Federation Residency Training Workshop, Phoenix, AZ, December 2002
16. "The Who-What-When-How of Training" National Abortion Federation Residency Training Workshop, Phoenix, AZ, December 2002
17. "Gender Discrimination in Obstetrics and Gynecology: the Impact on recruiting men and retaining women" APGO Faculty Development Seminar, Kapalua, Maui, January 2003
18. "Clinical Issues in First Trimester Abortion", Medical Students for Choice, Annual Meeting, Seattle, WA, April 2003
19. "Clinical Issues in Second Trimester Abortion", Medical Students for Choice, Annual Meeting, Seattle, WA, April 2003
20. "Medical Student and Resident Education in Abortion" National Abortion Federation, Annual Meeting, Seattle, WA, April 2003
21. "The Who-What-When-How of Training", National Abortion Federation Residency Training Workshop, Chicago, March, 2004
22. "Alternatives to Hysterectomy" Medica Symposia Conference, Maui, Hawaii, December, 2004



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23. "Contraceptive Options for Women over 40" Medica Symposia Conference, Maui, Hawaii, December, 2004
24. "Gynecologic Procedures" Medica Symposia Conference, Maui, Hawaii, December, 2004
25. "Workup and Management of Postmenopausal Bleeding" Medica Symposia Conference, Maui, Hawaii, December, 2004
26. "Transcervical Female Sterilization", PPFA Medical Directors Conference, Steamboat Springs, CO, March, 2005
27. "Multi-site Studies", Family Planning Fellowship Directors Meeting, San Francisco, CA, May, 2005
28. "Infections in Medical Abortion" Annual Meeting of the National Abortion Federation, San Francisco, CA April, 2006
29. "Technique of IUD insertion to minimize perforation risk" PPFA teleconference, November 2006
30. "Requiring abortion training in Ob/Gyn residency: Does it effect recruitment?" 34<sup>th</sup> Annual national meeting of the North American Society for Psychosocial Obstetrics and Gynecology, Portland, OR February 2007
31. "First Trimester Abortion Technique", Medical Students For Choice National Meeting, Tampa, FL, March 2007
32. "Review of Essure Procedures", ASRM, Washington DC, October 2007
33. "Abortion training in Ob/Gyn Residencies" Medical Students for Choice National Meeting, Minneapolis, MN, April 2008
34. "OHSU Feticide Policy" Family Planning Fellowship Annual meeting, New Orleans, LA, May 2008
35. "Balancing Life and Work Panel" ARHP annual meeting, Washington DC, Sept 2008
36. "Update on pain management in surgical abortion". National Abortion Federation annual meeting, Portland, OR, April, 2009.
37. "Management of the non-lethal anomaly". National Abortion Federation annual meeting, Portland, OR, April, 2009.
38. "Pain Management of Gynecologic Procedures" Grand Rounds, Northwestern University, Ob/Gyn department, Chicago, IL May 2009
39. "Essure Review", American Society of Reproductive Medicine annual meeting, Atlanta GA, October 2009
40. "Issues in second trimester abortion", MSFC annual meeting, Salt Lake City, UT, November 2009
41. "Practitioners Perspective Panel", MSFC annual meeting, Salt Lake City, UT, November 2009
42. "Abortion Panel", MEDC meeting, Salt Lake City, UT, March 2010
43. "IUD Review", Grand Rounds, University of Utah Department Ob/Gyn, Salt Lake City, UT, March 2010
44. "Hysteroscopic Sterilization Review" MEDC annual meeting, Las Vegas, NV, March 2011

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45. "Patient Safety in Abortion Care", MEDC annual meeting, Las Vegas, NV, March 2011
46. "Pain management in gyn procedures" Grand Rounds, Dept Ob/Gyn, Wayne State University, Detroit MI, March 2011
47. "Values clarification workshop" Residents, Dept Ob/Gyn, Wayne State University, Detroit MI, March 2011

#### International

1. "Background/Historical Context," "Medications: Mifepristone, Misoprostol and Methotrexate," "Protocol," "Patient Management," National Abortion Federation & Planned Parenthood Federation of America "Mifepristone 2000," Vancouver BC. September 2000
2. "IUD Review", Grand Rounds, Ob/Gyn Department, University of Zambia, Lusaka, Zambia, September 2010
3. "Contraception Review" Hospital Staff Meeting, Gimbie Adventist Hospital, Gimbie Ethiopia, November 2010
4. "Post abortion IUCDs to reduce subsequent pregnancies" International Family Planning Conference, November 2011, Dakar, Senegal
5. "Update on USA contraception research" Shanghai Institute of Planned Parenthood Research, October 2013

#### **IV. SERVICE**

##### **Membership in Professional Societies:**

Oregon Medical Association, 1983 - present

American College of Obstetrics and Gynecology, Oregon Section, 1983-present

Multnomah County Medical Society, 1983 - present

Association of Reproductive Health Professionals, 1983 - present

Association of Professors in Gynecology and Obstetrics, 1983 - 1993

American Fertility Society, Elected 1984

National Abortion Federation 1996 - present

National Abortion Rights Action League, 1987 - present

Pacific Northwest Obstetrical and Gynecological Society, 1989 - present

Pacific Coast Obstetrical and Gynecological Society, 1993 – present

Society of Family Planning, 2005 - present

**Appointed or Elected Positions in Professional Societies:**

American College of Obstetrics and Gynecology, Oregon Section

Advisory Committee Member, 1984-1987

Program Coordinator, 1984-1987

Vice Chair, 1997-2000

Chair, 2000-2003

Program Chair, Annual Meeting, April 1998

Program Chair, Annual Meeting, April 1999

Program Chair, Annual Meeting, April 2000

Program Chair, Annual Meeting, April 2001

Program Chair, Annual Meeting, April 2002

Program Chair, Annual Meeting, April 2003

American College of Obstetrics and Gynecology, District VIII

Advisory Council member, 1997-2003

Junior Fellow Advisor, 2000-2003

Association of Reproductive Health Professionals

Program Planning Committee, 1998

Co-Chair, Planning Committee, 2009

National Abortion Federation

Co-Chair, Risk Management Seminar, 1999

Co-Chair of Scientific Session at NAF National Meeting

Atlanta GA, April 1998

Vancouver BC, April 1999

Pittsburgh PA, April 2000

St. Louis MO, April 2001

San Jose, CA, April 2002

Seattle, WA, April 2003

New Orleans, LA, April 2004

Montreal, Canada, April 2005

San Francisco, CA, April 2006

Boston, MA, April 2007

Minneapolis, MN, April 2008

Portland, OR, April 2009

Philadelphia, PA, April 2010

Chicago, IL, April 2011

Vancouver BC, April 2012

Pacific Coast Obstetrical and Gynecological Society

Program Chair, 1998 meeting

Member program committee, 1997-2003

Program Chair, 2001 meeting

Society for Family Planning

President Elect, 2007-2009

Chair Scientific Committee, 2007-2009

President, 2009-2011

20

Immediate Past President, 2011-2013

**Editorial and Ad Hoc Review Activities:**

Member, Editorial Board

*Contraception* 2014 - 2018

Journal Reviewer Experience

*American Journal of Obstetrics and Gynecology*

*Obstetrics and Gynecology*

*Journal of American Women's Association (JAMWA)*

*British Journal of Obstetrics and Gynecology*

*New England Journal of Medicine*

*International Journal of Obstetrics and Gynecology*

*Contraception*

Section Editor

*Current Women's Health Reports*, General Gynecologic Issues Section, 2001, 2002, and 2003

**Committees:**

International/National

Norplant Training in the Community, Panel Member, Dallas, Texas, April 1996

Planned Parenthood Federation of America

National Medical Committee, April 1996 - 2002

Primary Care Subcommittee, April 1996 - 2002

Nominating Committee for National Medical Committee, 1997, 1999

Chair, Nominating Committee for National Medical Committee, 2001

Member, National Board of Directors, 2017-2023

Secretary, National Board of Directors, 2018-2021

Chair, Federation Governance Committee, 2019-2022

Co-chair, Accreditation and Quality Committee, 2021-2025

National Abortion Federation

Planning Committee, Risk Management Seminar, Denver CO, September 1999

American College of Obstetrics and Gynecology,

Oregon Section

Advisory Committee Member, 1984-1987

District VIII

Advisory Committee 2000-2003

Junior Fellow Advisor 2000-2003

Association of Reproductive Health Professionals

Program Planning Committee, 1998, 2008

21

Regional

Pacific Coast Obstetrical and Gynecological Society, 1993 - present  
Member program committee, 1997-2003

Institutional

OHSU School of Medicine

Grievance Committee, September 1985 - June 1989  
Joint Conference Committee on Graduate Medical Education, January 1987 - 1994  
Student Health Advisory Committee, January 1988 - June 1994  
Curriculum Review Task Force, Transition to Residency Course, February 1991 - 1993  
Faculty Council, August 1991 - June 1997  
Faculty Senate, June 1994- June 1996  
Search Committee for Director for Maternal Fetal Medicine Division, 1998  
Promotion and Tenure, October 1996 - 2002  
Women's Health Student Interest Group, Faculty Advisor, 1998 - 2010  
Medical Students for Choice, OHSU Chapter, Faculty Advisor, 1998 - 2010  
School of Medicine Awards Committee, 2002-2007  
Faculty Practice Plan Board of Directors, elected member, 2009-2012

Departmental

Executive Committee 1988-2013  
Promotion and Tenure Committee 1995-2005  
Clinical Care Committee 1999-2007  
Education Committee 1999-2013  
Combined Education Committee 1983-1995

Hospital

Medical Records Committee, September 1983 - 1987  
Ambulatory Care Committee, July 1987 - July 1990  
Operating Room Committee, 1988 - 1992  
University Medical Group  
Finance Committee, April 1993 - April 1997  
Clinical Practice Committee, May 1994 - April 1997  
Board of Directors, Specialty Care Representative, March 1998 - 2001  
Compensation Committee, 1998  
Board of Directors, 1998 - 2001  
IPCO Advisory Board, 1995 - 1998  
University Hospital North, Ambulatory Surgery Move Task Force, March 1997 - June 1998  
Surgical Services Committee, 1998 - 2003  
Ambulatory Surgery Management Group, 2000 - 2003.

**Local, State, National Recognition for Clinical Excellence:**

Selected as one of the "Top-Rated Physicians in America", in Guide to Top Doctors, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012  
Named as one of the "Best Doctors for Women-coast to coast", *Ladies Home Journal*, April, 2002  
Selected as one of "Our Best Doctors" by Portland physicians, *Portland Monthly*: 2004, 2005, 2006, 2007, 2008,

22

2009, 2010, 2011, 2013

"Pioneer and Leader Award", for introduction of Essure in PPFA, September 2004

**Clinical Care Awards:**

Rose Awards: numerous

**Community Service:**

Birth Home, Board of Directors, Portland OR, 1982 - 1987

Planned Parenthood Columbia Willamette

Medical Committee, April 1984 - 2013

Chairman Medical Committee, June 1991 - 1994

Board of Directors, July 1991 – 1994

Portland Feminist Women's Health Center, Medical Advisor, 1983 - 1987

Oregon State Health Division

Out of Hospital Birth Task Force, September 1985 - November 1987

Direct Entry Midwifery, Board of Directors, 1993 - 1999

Family Planning Consultant, April 1997 - 2013

Teen Pregnancy Prevention Task Group Member, December 1996 - 1998

Region X Chlamydia Project Member, February 1997 - 1999

Population Services International

Advisory Committee on Emergency Contraception Promotion Project 2000-2001

**V. TEACHING (OHSU Educator's Portfolio):**

**Overview of your Role as an Educator:**

Almost all of my clinical activities occur with a learner present. I see patients at the Center for Women's Health with third year medical students, provide care at Planned Parenthood with Ob/Gyn residents and Family Planning fellows, perform surgery and deliver babies with medical students and residents. My philosophy of teaching is to allow learners to perform to their abilities and to encourage assumption of increasing responsibility as skills and knowledge grow. I believe that learning occurs best when individuals are given autonomy (commensurate with their training) to provide medical care. I attempt to foster this type of learning by providing feedback during and after the learners care for patients. In surgery, that occurs while directing every action of the learners. In the clinic setting, the learners have more independence to develop their skills without step by step direction.

**Scholarship of Teaching:**

Curriculum Development

I developed the program objectives for the Family Planning Fellowship. This document was submitted to the Buffett Foundation, and we received approval as a training site.

Educational Conference Presentations

See "Invited Lectures, Conference Presentations or Professorships:" (above)

Classroom Teaching (Since 1995, and not cited in Local Presentations above)

Principles of Clinical Medicine,

“Obstetric Physical Examination”, 1995, 1996, 1997, 1998, 2000, 2001, 2002, 2003, 2004, 2005  
Pelvic/GU Examination Instructor, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004,  
2005, 2006, 2007, 2008, 2009, 2010

Gross Anatomy Class – MS I Course:  
Instructor 2001, 2003, 2004

Physician Assistant Curriculum  
“Breast Disease” 1999, 2001  
“Contraception” 1999, 2001  
“Ectopic Pregnancy” 2003, 2004, 2005, 2006, 2007

Human Growth and Development - MS II Course  
“Contraception, Abortion, and Sterilization” 1995-2012  
“Female Infertility” 1995-2001  
“Abnormal Menstrual Cycles” 1995-2004  
“Panel: Population Growth”, 1995-1998

Pediatric Resident Noon Conference Series  
“Contraception for Adolescents,” 1996, 1998, 2000, 2003  
“Evaluation and Management of Abnormal Bleeding in Adolescents,” 2000, 2002

Internal Medicine Resident Noon Conference Series  
“Contraception Review”, 2004

Students for Reproductive Choice Elective  
“Surgical Abortion Technique” 1997-2007

Women’s Health Care Nurse Practitioner Curriculum  
“Abortion Review” 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003  
“Benign Breast Disease” 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003  
“Oral Contraceptives and Emergency Contraception” 2002, 2003

Nurse-Midwifery Curriculum  
“Shoulder Dystocia” 1995-2016  
“Breech Presentation” 2006, 2008, 2010, 2012, 2014, 2016

Family Practice Resident Noon conference  
“Contraception Update” 2003  
“Medical Abortion” 2003

Endocrinology Fellows Noon Conference  
“Contraceptive Review” 2005

Women’s Health Interest Group  
“Management of Breech Presentation” 2010

**Education Grants and Contracts:**

Fellowship in Family Planning, funded by the Buffett Foundation. This pays for the salary of two fellows (R5 & R6) and 10% of the faculty of the fellowship director, (split evenly with the assistant fellowship director)

**Effectiveness of Educational Activity:**

Evaluations from teaching activities are available.

**Mentorship:**

Served on the MPH thesis committee for Kim Goldsmith, 2003-2004.

Served as mentor of numerous residents for their research projects including Lisa Thomas, Alison Edelman, Neva Phair, Carla Picardo, Marni Kwiecen, Liz Morgan, Gary Burgoine, Stephanie Koontz, Gina Allison, Emily Drath

**Service and Membership of Educational Committees:**

Steering Committee for the Human Growth and Development Course, SOM, OHSU, 1995-2002

Course Development Committee, Transition to Internship, SOM, OHSU, 1998

Member, Thesis Advisor for Kim Goldsmith, candidate for MPH, 2003

**Honors and Awards for Education:**

Outstanding Teaching Award, presented by graduating chief residents, OB/GYN Department at OHSU, June 1992.

APGO/CREOG National Faculty Award, presented for excellence in teaching to one faculty member in the Ob/Gyn Dept. at OHSU each year, June 1993.

Excellence in Basic Sciences Teaching MSII Curriculum, OHSU, School of Medicine, 1994-1995.

Teaching Excellence Award, OHSU, School of Medicine, 1999-2000

J. David Bristow Award, OHSU, School of Medicine, Senior Class recognition to "one faculty member who exemplifies the ideals of the true physician as he/she conducts clinical practice with patients and colleagues", June 2001.

APGO/CREOG National Faculty Award, presented for excellence in teaching to one faculty member each year, June 2001

Planned Parenthood Federation of America, Affiliate Excellence Award given to one affiliate in the country for outstanding clinical teaching and research, 2003

Chosen as Faculty Marshal, OHSU School of Medicine Commencement Ceremony, June, 2004

Teaching Excellence Award, OHSU, School of Medicine, 2003-2004

Medical Students for Choice Faculty Mentor Award, presented at MSFC National meeting, Philadelphia, March, 2005

J. David Bristow Award, OHSU, School of Medicine, Senior Class recognition to "one faculty member who exemplifies the ideals of the true physician as he/she conducts clinical practice with patients and colleagues", June 2007.

The Leonard Tow Humanism in Medicine Award, June 2007



25

Chosen as Faculty Marshal, OHSU School of Medicine Commencement Ceremony, June, 2008

Outstanding Teacher Award, presented by graduating chief residents, OB/GYN Department at OHSU, June 2009.

Medical Students for Choice Faculty Mentor Award, presented at MSFC National meeting, Salt Lake City, UT, October 2009.

Robert Hatcher Family Planning Mentor Award, Society of Family Planning, 2015

Mark Nichols Award created to honor the top graduating medical student at OHSU going into an Ob/Gyn Residency, 2016

# Exhibit 15

1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
Civil Rights Division Chief  
5 ANDREW R.W. HUGHES, WSBA #49515  
LAURYN K. FRAAS, WSBA #53238  
6 Assistant Attorneys General  
TERA M. HEINTZ, WSBA #54921  
7 (application for admission forthcoming)  
Deputy Solicitor General  
8 800 Fifth Avenue, Suite 2000  
Seattle, WA 98104-3188  
9 (206) 464-7744

10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
SARAH W. PRAGER, MD,  
MAS, IN SUPPORT OF  
MOTION FOR PRELIMINARY  
INJUNCTION

1 I, Sarah W. Prager, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am a professor of Obstetrics and Gynecology at the University of  
5 Washington (UW). I am the Director of the Family Planning Division and  
6 Complex Family Planning Fellowship. I am board-certified in Obstetrics and  
7 Gynecology and Complex Family Planning with the American Board of  
8 Obstetrics and Gynecology. I have clinical practices at UW Medical Center and  
9 the Cedar River Clinic in Renton.

10 3. I received my Master of Advanced Studies in Clinical Research  
11 from the University of California, San Francisco in 2006, my medical degree  
12 from the University of Texas Southwestern Medical School in 2000, and my  
13 BA from Princeton University in 1993. I currently chair the Clinical Policies  
14 Committee for the National Abortion Federation and I co-authored the Early  
15 Pregnancy Loss Practice Bulletin for the American College of Obstetricians and  
16 Gynecologists (ACOG). I have co-authored six topics on early pregnancy loss  
17 for UpToDate. I am a Fellow of the American College of Obstetricians and  
18 Gynecologists (FACOG), was the Chair of the Washington Section of ACOG,  
19 and am currently the Secretary of District VIII for ACOG, as well as the co-Chair  
20 of the Abortion Access and Training Working Group. A copy of my CV is  
21 attached hereto as Exhibit A.  
22

1           4. In my practice, I provide the full spectrum of general obstetrics and  
2           gynecological care. My special clinical focus is complex family planning and  
3           helping pregnant people navigate their needs around abortion, contraception, and  
4           miscarriage. As part of my practice, I regularly prescribe medications for  
5           miscarriage care and for medication abortions, including mifepristone. I also  
6           supervise the use of medication for miscarriage care and medication abortions by  
7           other medical professionals at the UW Medical Center, including by other  
8           physicians, nurse practitioners, midwives, physicians' assistants, and residents.

9           5. I submit this declaration in support of Plaintiff's Motion for  
10          Preliminary Injunction.

11          **Mifepristone**

12           6. I am familiar with the drug mifepristone. As an OB/GYN, I  
13           prescribe mifepristone for my patients and have done so since approximately  
14           2000, after it was approved by the FDA and once I was in residency.

15           7. Mifepristone is one of a two-drug regimen prescribed for medication  
16           abortions and miscarriage care. The drug is also used for purposes of induction  
17           in cases of second- and third-trimester loss.

18           8. The two-drug regimen for medication abortion up to 70 days  
19           involves one dose of mifepristone and one dose of misoprostol. A patient first  
20           takes mifepristone, which terminates a pregnancy by blocking the hormone  
21           progesterone, which is necessary for the maintenance of a pregnancy. Between  
22

24 and 48 hours later, the patient then takes misoprostol, which causes cramping and bleeding to expel the contents of the uterus. This process is similar to a miscarriage.

9. The use of mifepristone in combination with the drug misoprostol is considered the gold standard in the medical management of miscarriage and medication abortions. This has been the case since the early 2000s, when peer-reviewed studies demonstrated that use of the two-drug regimen is both safer and more effective than use of a one-drug regimen of misoprostol alone.<sup>1</sup> Although it

---

<sup>1</sup> Bygdeman, M., Swahn, M.L., *Progesterone receptor blockage. Effect on uterine contractility and early pregnancy*, Contraception 32:45-51(1985); Blanchard, K., Winikoff, B., Ellertson, C., *Misoprostol used alone for the termination of early pregnancy*, Contraception 59:209-217 (1999); Cameron, I.T., Michie, A.F., Baird, D.T., *Therapeutic abortion in early pregnancy with antiprogestogen RU 486 alone or in combination with prostaglandin analogue (gemeprost)*, Contraception 34(5):459-468 (1986); Jain, J.K., Dutton, C., Harwood, B., Meckstroth, K.R., Mishell, D.R., *A prospective randomized, double-blinded, placebo-controlled trial comparing mifepristone and vaginal misoprostol to vaginal misoprostol alone for elective termination of early pregnancy*, Human Reproduction 17(6):1477-1482; (2002); Swahn, M.L., Ugocsai, G., Bygdeman, M., Kovacs, L., Belsey, E.M., Van Look, P.F.A., *Effect of oral prostaglandin E2 on uterine contractility and outcome of treatment in*

1 is possible to prescribe misoprostol alone for the medical management of  
 2 miscarriages and for medication abortions, it requires higher and more frequent  
 3 doses, with increased undesirable patient side effects, such as nausea, cramping,  
 4 bleeding, and flu-like symptoms.

### 5 **Treatment for Medication Abortion**

6 10. When patients in early pregnancy contact my office seeking  
 7 abortion care, my staff schedules them for either an in-person or telehealth  
 8 consultation with me. I begin each visit by reviewing the patient's medical history  
 9 and symptoms to determine the kinds of abortion for which they are eligible. I  
 10 then discuss with my patient the risks, benefits and alternatives for each kind of  
 11 abortion care for which they are eligible and answer any questions they may have  
 12 to ensure that they have the information they need to make an informed decision  
 13 about their care.

14 11. If they are eligible for, and choose, a medication abortion, we  
 15 proceed with the visit for such care.

16 12. I discuss the medication abortion process and discuss the Patient  
 17 Agreement Form with the patient. After answering any questions, I ask whether  
 18

19 \_\_\_\_\_  
 20 *women receiving RU 486 (mifepristone) for termination of early pregnancy,*  
 21 *Human Reproduction 4(1):21-28 (1989); Zheng, S.R., RU486 (mifepristone):*  
 22 *clinical trials in China, Acta Obstet Gynecol Scand Suppl 149:19-23 (1989).*

1 they consent to a medication abortion, and if they do, I confirm that consent in  
2 their medical record.

3 13. I then go over again the instructions for how and when to take their  
4 medication, what the follow-up process is, what they should do if they experience  
5 any of the (very rare) serious complications associated with mifepristone or  
6 misoprostol, and answer any questions they may have.

7 14. In the course of the visit, I also have to review and have the patient  
8 sign the Patient Agreement Form. The Patient Agreement Form is duplicative of  
9 the information contained in the FDA's Medication Guide, which is dispensed to  
10 the patient with the medication.

11 15. I also prescribe mifepristone, in combination with the drug  
12 misoprostol, to patients who are experiencing a miscarriage. Using this two-drug  
13 regimen to manage miscarriage is the gold standard for miscarriage management  
14 and has been the basic standard of care at UW for approximately five years.<sup>2</sup>

15 16. Under the REMS, the patients I treat for miscarriage management  
16 are required to sign the same Patient Agreement Form as patients receiving  
17 mifepristone for a medication abortion. This is confusing and often distressing  
18

19 \_\_\_\_\_  
20 <sup>2</sup> See Schreiber, C.A., Creinin, M.D., Atrio, J., Sonalkar, S., Ratcliffe, S.J.,  
21 Barnhart, K.T., *Mifepristone pretreatment for the medical management of early*  
22 *pregnancy loss*, N Engl J Med 378(23):2161–70 (2018).



1 for patients. I have had patients who have been upset at having to sign a form  
2 about medical abortion when they are, in fact, experiencing a miscarriage.

3 17. The way that I counsel patients regarding taking mifepristone for  
4 medication abortion or miscarriage management—discussing risks and benefits,  
5 explaining the treatment, and obtaining patient consent—is essentially the same  
6 as how I or any other medical provider counsels a patient on any medical  
7 procedure. This is absolutely standard practice in medicine, taught in medical  
8 schools and residences, and reinforced through practice. The Patient Agreement  
9 Form is duplicative of the counseling I already do and is completely unnecessary.

10 18. The Patient Agreement Form can also make counseling *more*  
11 difficult in many circumstances. Some patients, for instance, are confused as to  
12 why I am asking them to sign an agreement form for a drug that I am explaining  
13 to them is very safe. In those instances, the Patient Agreement Form acts to  
14 unnecessarily heighten patient worry and stress. When I am treating patients who  
15 are non-English speakers, the Patient Agreement Form creates an item that must  
16 be explained and worked through with the translator and creates additional  
17 burden as well as confusion.

18 19. Further, in a post-*Roe* era in which there is increasing  
19 criminalization of abortion and general chaos of abortion laws across the country,  
20 I have growing concern about the Patient Agreement Form for my out-of-state  
21 patients. While I recognize that my treatment notes will always be part of my  
22

1 patients' medical charts, the fact that I am required to have patients affirmatively  
2 sign a document (that must be given to them and placed in their medical chart)  
3 stating that they are choosing to have a medication abortion creates an additional  
4 and unnecessary risk to patients that has no grounding in medicine or science.

5 20. In the course of my medical career, I have counseled and treated  
6 hundreds, if not thousands, of patients with mifepristone for medication abortion  
7 or miscarriage management. I am not aware of any of those patients experiencing  
8 a serious adverse reaction or death. It is among the safest drugs I prescribe my  
9 patients.

10 **The REMS Cannot be Justified by any Medical or Safety Concerns**

11 21. Mifepristone is one of a small number of medications that the FDA  
12 subjects to a Risk Evaluation and Mitigation Strategy (REMS).

13 22. The REMS require that mifepristone be dispensed by or under the  
14 supervision of a certified prescriber, or by certified pharmacies for prescriptions  
15 issued by certified prescribers, and the use of Pharmacy, Prescriber (or Provider)  
16 and Patient Agreement forms. Those updates went into effect on January 3, 2023.

17 23. REMS are typically applied to inherently dangerous drugs like  
18 opioids. Mifepristone, however, is extremely safe. Indeed, the FDA's own  
19 publications reviewing the safety and efficacy of mifepristone show that there is  
20 no scientific need for mifepristone to be subject to a REMS.

24. Mifepristone is safer for patients than acetaminophen (Tylenol), for example. Studies show that less than one percent of patients who take mifepristone for abortion care require hospitalization for adverse events or complications. And as I noted above, I am not aware of any of the hundreds (if not thousands) of patients I have treated with mifepristone over the last 23 years having had a serious adverse drug event or death. By contrast, acetaminophen is the most common cause of liver transplantation in the United States, and is responsible for 56,000 emergency room visits, 2,600 hospitalizations, and 500 deaths per year in the United States.<sup>3</sup> But no REMS apply to the use of acetaminophen, and it can be obtained without a prescription at pharmacies and many other stores.

25. Furthermore, mifepristone is prescribed in some endocrinological (non-gynecological) situations at higher doses, including for conditions like Cushing's Disease. There are no REMS associated with those uses of mifepristone.

26. Because of mifepristone's superior safety profile, leading medical organizations including the American College of Obstetricians and

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<sup>3</sup> Suneil Agrawai and Babek Khazaeni, *Acetaminophen Toxicity*, National Library of Medicine (Aug. 1, 2022) *available at* <https://www.ncbi.nlm.nih.gov/books/NBK441917/#:~:text=It%20is%20responsible%20for%2056%2C000,is%20contained%20in%20combined%20products>.

1 Gynecologists (ACOG), the American Academy of Family Physicians (AAFP),  
 2 and the American Medical Association (AMA) have called for the removal of the  
 3 mifepristone REMS. In 2016, ACOG concluded “that a Risk Evaluation and  
 4 Mitigation Strategy (REMS) is no longer necessary for mifepristone, given its  
 5 history of safe use. The REMS requirement is inconsistent with requirements for  
 6 other drugs with similar or greater risks, especially in light of the significant  
 7 benefit that mifepristone provides to patients.”<sup>4</sup>

8 27. In 2018 AAFP similarly concluded that “the REMS restrictions are  
 9 not based on scientific evidence”; are overly burdensome on practitioners and  
 10 impede patient access to care, particularly “for patients who might prefer to go to  
 11 their own physician and for rural patients who have no other access points beyond  
 12 their local physician”; cause “delays in care, thereby increasing second-trimester  
 13 and surgical abortions, both of which have increased complication rates”; and  
 14 create “a barrier to safe and effective off-label uses of mifepristone, such as for  
 15 anti-corticoid treatment of Cushing’s disease, term labor induction, and  
 16 miscarriage management[.]”<sup>5</sup>

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17  
 18 <sup>4</sup>ACOG Statement on Medication Abortion,  
 19 [https://www.acog.org/news/news-releases/2016/03/acog-statement-on-](https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion)  
 20 [medication-abortion](https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion).

21 <sup>5</sup>Am. Acad. of Family Phys. 2018 Congress of Delegates, *Resolution*  
 22 *No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy*

28. In 2021, the AMA urged the FDA to “eliminate the requirement for patients to sign a form to get the drug” and “lift the requirement that prescribers acquire a certification from the manufacturer,” noting that “[b]arriers to accessing mifepristone do not make care safer, are not based on medical evidence, and create barriers to patient access to essential reproductive health care.”<sup>6</sup>

29. The mifepristone REMS do nothing to enhance patient safety because they are redundant to what healthcare providers already do anyway. The provider certification form, for example, requires the provider to certify that they can accurately date a pregnancy, diagnose an ectopic pregnancy, and treat complications that may arise or refer to someone who could. But any provider who might provide a medication abortion—including obstetricians, gynecologists, family physicians, primary care physicians, and certified nurse midwives—are already extensively trained in pregnancy dating, ectopic risk

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(REMS) Categorization on Mifepristone, available at <https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf>.

<sup>6</sup>Letter to Robert Califf, MD (Jun. 21, 2022), available at <https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/lf.dr.zip/2022-6-21-Joint-ACOG-AMA-Letter-to-FDA-re-Mifepristone.pdf>.

1 factors, and care coordination. The provider certification thus does not provide  
2 any additional patient safety.

3 30. Similarly, as I discussed above, the Patient Agreement Form is  
4 duplicative of information that providers are already required to provide patients,  
5 and therefore contributes nothing to enhancing patient knowledge or improving  
6 patient care.

7 31. In fact, the Patient Agreement Form can cause patient confusion for  
8 multiple reasons. First, the Patient Agreement Form requires the patient to  
9 declare they “have decided to take mifepristone and misoprostol *to end my*  
10 *pregnancy.*” But mifepristone is not just used for medication abortion; it is also  
11 the standard of care for medically managing miscarriage. Second, the Patient  
12 Agreement Form requires the patient to declare they “will take the misoprostol  
13 tablets 24 to 48 hours after I take mifepristone.” But emerging medical evidence  
14 suggests that misoprostol may sometimes be appropriately taken fewer than 24  
15 hours after taking mifepristone, and sometimes even concurrently. Accordingly,  
16 for those patients whose doctors direct misoprostol be taken fewer than 24 hours  
17 after mifepristone, the Patient Agreement Form is contrary to their doctor’s  
18 advice and may lead to confusion. And, as I noted above, the Patient Agreement  
19 Form can also cause additional patient stress as the form causes some to worry  
20 that the medication is actually more dangerous than it is. The Patient Agreement  
21  
22

1 Form can also make counseling a patient more difficult, particularly in situations  
2 in which a translator is being used.

3 **Burdens and Harms of Complying with January 2023 REMS for**  
4 **Mifepristone**

5 32. In addition to not being justified by science and not providing any  
6 benefits to patient safety, the REMS conditions impose substantial burdens and  
7 harms on health care practitioners.

8 33. As the Director of the Family Planning Division and Family  
9 Planning Fellowship at UW, part of my responsibilities have been to lead,  
10 strategize and operationalize UW's compliance with the FDA's recently-updated  
11 REMS on dispensing mifepristone.

12 34. Based on this work, I have seen firsthand how implementing the  
13 REMS into patient care creates a substantial burden to medical professionals and  
14 health care facilities, which will continue to impede access to safe, legal abortion  
15 care and effective miscarriage management for all Washingtonians.

16 35. UW has organized a workgroup to work through the exceedingly  
17 complicated problem of integrating the 2023 REMS requirements into patient  
18 care at UW Medicine. The workgroup is multidisciplinary, including  
19 approximately twenty professionals, including those responsible for regulatory  
20 compliance, information technology specialists, clinicians, pharmacists,  
21 University management, and legal personnel. The workgroup has been meeting  
22

1 for 4 or 5 months, and the group has expended hundreds of hours on  
2 implementing the REMS. This includes creating and instituting the dual signature  
3 Patient Agreement form, and implementing a system for confirming the proper  
4 certifications at the provider and pharmacy level. The IT team has had to  
5 determine how to build out the process; figure out what the Patient and Prescriber  
6 Agreement forms look like and how to integrate them into UW systems;  
7 determine how to keep track of and where to house a list of certified prescribers,  
8 and how pharmacies can access the list in order to confirm prescriber certification  
9 before filling the prescription. Once that process is in place, there will need to be  
10 training and education to all providers and other involved personnel on how to  
11 use the new system.

12 36. Despite the workgroup's progress, significant work remains to be  
13 done to implement all the requirements of the 2023 REMS. I have spent  
14 approximately 20-40 hours on this work, which includes significant intersecting  
15 efforts with the entire workgroup. I estimate that other members of the workgroup  
16 have similarly averaged 20-40 hours in this work. I cannot imagine many smaller  
17 medical organizations, community hospitals, or local pharmacies will be able to  
18 devote such intensive resources to comply with these new regulatory demands.

19 37. The harms from the REMS extend beyond the difficulties in  
20 complying with the requirements. The REMS implicitly discourage providers  
21 from using mifepristone for miscarriage care and medication abortions. As noted  
22



1 above, REMS are generally only placed on dangerous drugs liked opioids and the  
2 existence of the REMS coupled with the provider certification creates a  
3 disincentive to prescribe a very safe medication. It also creates additional  
4 burdens. Whereas under the prior REMS, a single supervisory physician (like  
5 me) could obtain certification from the manufacturer and then oversee use of  
6 mifepristone by numerous other medical professionals in the same medical  
7 system, the new REMS require each individual provider to obtain certification if  
8 they will be prescribing via telehealth to a certified pharmacy. This part of REMS  
9 compliance has created a huge amount of additional work at UW as it takes time  
10 to identify the prescribers who need to complete a Provider Agreement; ensure  
11 that they review and sign it; and then ensure that it is given to the UW certified  
12 pharmacy.

13 38. Given the increasingly threatening and hostile environment  
14 surrounding abortion care—including threats of prosecution of abortion-care  
15 providers by other states and harassment and violence by anti-abortion  
16 activists—medical professionals are understandably hesitant to become certified  
17 and to identify as prescribing medication abortions. The REMS compound these  
18 fears, as certified prescribers must send their certification to each certified  
19 pharmacy at which they intend to prescribe. While pharmacies are required to  
20 keep these lists confidential, fears of a potential leak act as a significant deterrent  
21 to many doctors being willing to prescribe mifepristone—particularly in  
22

1 communities where there may be greater threats of anti-abortion violence, further  
2 burdening patient access to care.

3 39. These fears are particularly acute for doctors who hold medical  
4 licenses in multiple states, where abortion laws differ from Washington's. These  
5 providers fear that they may open themselves up to criminal prosecution or  
6 litigation in those states for providing abortion care in Washington. The same is  
7 true for some of our residents who come from states where abortion is now illegal  
8 and who plan to eventually practice medicine in those states. The REMS does not  
9 account for the growing number of threats and other types of targeted  
10 intimidation experienced by many abortion providers. Nor does the REMS  
11 consider the ever-increasing burden on patient access to abortion care.

12 40. Currently, almost half of all OB-GYN residents are training in states  
13 where abortion is now illegal or severely restricted. These residents now cannot  
14 get routine training in life-saving abortion care within their training programs,  
15 and are seeking that training elsewhere. Washington State has an obligation first  
16 to the clinicians training here, but also to clinicians who cannot access training  
17 elsewhere. The additional burden of the REMS makes operationalizing this  
18 training for out-of-state clinicians even more difficult.

19 41. Based on my professional experience and medical training, there is  
20 no scientific or medical basis for the mifepristone REMS program. The FDA's  
21  
22

1 decision to nevertheless continue placing these unnecessary and burdensome  
2 restrictions on a safe and effective drug, clearly demonstrates that the  
3 mifepristone REMS program is not needed to protect patients—but is instead  
4 intended to limit patient’s access to medication abortion.

5 I declare under penalty of perjury under the laws of the State of  
6 Washington and the United States of America that the foregoing is true and  
7 correct.

8 DATED this 20th day of February, 2023, at  
9 Istanbul, Turkey.<sup>7</sup>

10  
11 *Sarah Prager*  
Sarah W. Prager, MD, MAS

12  
13  
14  
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16  
17  
18  
19  
20  
21 <sup>7</sup> I live and work in Washington, but I am signing this declaration while  
22 traveling abroad.

# Exhibit A

**CURRICULUM VITAE**  
**SARAH PRAGER, M.D., M.A.S.**

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**PERSONAL DATA**

Place of Birth	New York City, New York
Citizenship	United States of America

**EDUCATION**

B.A.	Princeton University Princeton, New Jersey <i>Summa Cum Laude</i>	1989 – 1993
M.D.	University of Texas Southwestern Medical School Dallas, Texas	1996 – 2000
M.A.S.	University of California, San Francisco San Francisco, California	2004 – 2006

**POSTGRADUATE TRAINING**

Internship and Residency	Fletcher Allen Health Care University of Vermont Burlington, Vermont	2000 – 2004
Family Planning Fellowship	University of California, San Francisco San Francisco, California	2004 – 2006
Teaching Scholars Program	University of Washington Medical Center Seattle, Washington	2009 – 2010
Excellence in Family Planning Research Course	The Foundation for Excellence in Women's Health Care	1/31 - 2/6, 2014
Medical Education Research Certificate (MERC) Program	University of Washington Medical Center Seattle, Washington	2015 - 2017

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**FACULTY POSITIONS HELD**

Clinical Fellow	University of California, San Francisco San Francisco General Hospital San Francisco, California	2004 – 2006
Assistant Professor	University of Washington Department of Obstetrics and Gynecology	2006 – 2012
Adjunct Assistant Professor	University of Washington Department of Health Systems And Population Health	2007 – 2012
Adjunct Associate Professor	University of Washington Department of Health Systems And Population Health	2012 – 2018
Associate Professor	University of Washington Department of Obstetrics and Gynecology	2012 - 2018
Affiliate Faculty	Center for Excellence in Maternal and Child Health Epidemiology Department University of Washington	2016 - present
Professor	University of Washington Department of Obstetrics and Gynecology	2018 - present
Adjunct Professor	University of Washington Department of Health Systems And Population Health	2018 - present
Professor	St. Paul Hospital and Millennium Medical College Department of Obstetrics and Gynecology Addis Ababa, Ethiopia	2019 - present

**HOSPITAL/MEDICAL POSITIONS HELD**

Physician, Reproductive Health Services	Cedar River Clinic Renton, Washington	2006 – present
Family Planning Clinic Director	Harborview Medical Center Women's Clinic Seattle, Washington	2007 – 2010

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Family Planning Ryan Residency Program Director, 2007-2013 Associate Director, 2013-present	University of Washington Department of Obstetrics and Gynecology Seattle, Washington	2007 – present
Family Planning Clinic Director	University of Washington Family Planning Clinic in the Women's Health Care Center Seattle, Washington	2010 – present
Family Planning Division Director	University of Washington Department of Obstetrics and Gynecology Seattle, Washington	2013 - present
Fellowship in Family Planning Director	University of Washington Department of Obstetrics and Gynecology Seattle, Washington	2013 - present
Title X Director	Cedar River Clinics Washington	2017 – present
Fellowship in Family Planning Director	St. Paul Hospital and Millennium Medical College Department of Obstetrics and Gynecology Addis Ababa, Ethiopia	2019 - present

**HONORS AND AWARDS**

Merit Scholarship	University of Texas Southwestern Medical School	1996 – 2000
Outstanding Teacher Award	Fletcher Allen Health Care University of Vermont Burlington, Vermont	2003
Organon Research Award	Fletcher Allen Health Care University of Vermont Burlington, Vermont	2004
"Golden Eddy" Award for Outstanding Patient Education	University of Washington Seattle, Washington	2010
Faculty Research Mentoring Award	University of Washington Seattle, Washington	2011
Mentor of the Year Award District VIII	American Congress of Obstetricians and Gynecologists	2012

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Excellence in Resident Education	University of Washington Seattle, Washington	2008, 2009, 2011, 2016
Nominated for UW Medicine Mentoring Award	University of Washington Seattle, Washington	2016
Women of Courage Honoree	University of Washington Women's Center Seattle, Washington	2017

**BOARD CERTIFICATION**

Obstetrics and Gynecology American Board of Obstetrics and Gynecology	2005 – present
Complex Family Planning American Board of Obstetrics and Gynecology	2022 - present

**CURRENT LICENSURE**

State of Washington; Physician and Surgeon	2006 – present
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**DIVERSITY, EQUITY AND INCLUSION ACTIVITIES**

Member	Society of Family Planning DEI Working Group	2019 - 2022
Member	UW OBGYN Department DEI Committee Subcommittee on Culture and Policy	2020 - present
Small Group Facilitator	UW White Caucus Group Sessions held throughout the Summer of 2020 for interested UW faculty and staff	Summer 2020
Small Group Co-Facilitator	From Ally to Antiracist Course conducted for UW faculty/staff 4 weekly sessions in January, 2021. Continued monthly meetings for small group participants	Jan - June, 2021
Small Group Co-Facilitator	White Antiracist Group Course conducted for UW faculty/staff 6 monthly sessions from July - December, 2021. Extended by participant request	2021 - present
Facilitator	UW Complex Family Planning Division DEI Caucuses	2020 - 2021

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Member	National Abortion Federation DEI Committee	2021 - present
Co-Facilitator	UW White Antiracist Group (WAG) UWMC-led group with new sessions every 6 months.	2021 - present

**PROFESSIONAL ORGANIZATIONS**

Member	Medical Students for Choice	1996 – present
Member	Planned Parenthood Federation of America	2000 – present
Member	American Congress of Obstetricians and Gynecologists (ACOG)	2000 – present
Member	National Abortion Federation	2004 – present
Member	Physicians for Reproductive Health	2004 – present
Member	Society for Family Planning	2006 – present
Member	Association of Reproductive Health Professionals	2006 – 2018
Member	Seattle Gynecology Society	2008 – present
Member	Washington State Medical Association	2008 – present
Member	European Society for Contraception And Reproductive Health	2009 – present
Member	Ethiopian Society of Obstetricians and Gynecologists (ESOG)	2019 - present

**TEACHING RESPONSIBILITIES**Curricula*International Curricula*

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Curriculum Development for the following courses: 2005 – 2006  
 Ectopic Pregnancy, Hydatidiform Mole, Spontaneous Abortion,  
 Vertex Presentation, Vertex Delivery Mechanism.  
 Hue Medical Facility, Vietnam/University of California, San Francisco

Curriculum Consultant 2009 – present  
 Immediate Postpartum IUD Insertion Training  
 Population Services International, Washington, D.C.

Curriculum Development 2019 - present  
 Fellowship in Family Planning  
 St. Paul Hospital Millennium Medical College  
 Addis Ababa, Ethiopia

Creation and Administration, Oral and Written Boards 2020 - present  
 Fellowship in Family Planning  
 St. Paul Hospital Millennium Medical College  
 Addis Ababa, Ethiopia

*National Curricula*

Content Creator and Lead Educator 2014 - present  
 Inserting Long Acting Reversible Contraception (LARC) Immediately After Childbirth. eLearning  
 Course, Independent Study, 2014.  
[http://www.cardeaservices.org/resourcecenter/inserting-long-acting-reversible-contraception-larc-immediately-after-childbirth.](http://www.cardeaservices.org/resourcecenter/inserting-long-acting-reversible-contraception-larc-immediately-after-childbirth)

Curriculum Director and Lead Educator 2008 – present  
 Training, Education and Advocacy in Miscarriage Management (TEAMM)  
<https://www.miscarriagemanagement.org/>

Member 2017 - present  
 Ryan Program Curriculum Advisory Committee  
<https://www.innovating-education.org/category/early-pregnancy-loss/>

*ACOG Curricula*

Course Director May 2008  
 Hands-On Office-Based Gynecologic Procedures  
 ACOG Annual Clinical Meeting, New Orleans, Louisiana

Course Co-Director 2010 and 2011  
 Family Planning 2011: Contraceptive Challenges, Controversies and Evidence  
 ACOG Annual Clinical Meeting, San Francisco, California and Washington, D.C.

*Fellow Curriculum*

Fellowship and Curriculum Director 2014 – present

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Fellowship in Family Planning  
University of Washington Medical Center, Seattle, Washington

Fellowship Director 2019 – present  
Fellowship in Family Planning  
St. Paul Hospital and Millennium Medical College, Addis Ababa, Ethiopia

*Resident Curricula*

Program and Curriculum Director 2007 – 2013  
Associate Director 2013 - present  
Ryan Residency Training Program in Family Planning  
University of Washington Medical Center, Seattle, Washington

Global Health Curriculum Committee 2009 – 2014  
Global Health Curriculum in Women's Health  
Obstetrics and Gynecology Residency Program  
University of Washington, Seattle, Washington

*Medical School Curricula*

Course Director 2007 – 2018  
OB 550 Elective: Voluntary Pregnancy Termination  
University of Washington School of Medicine, Seattle, Washington

Medical Student Lecturer 2008 – present  
HuBio 565 Lifecycles: Contraception and Abortion (4 hours)  
University of Washington School of Medicine, Seattle, Washington

Course Co-Director (with Vicki Mendiratta and Michael Fialkow) 2011 – present  
OB 505 Elective: OB GYN Preceptorship  
University of Washington School of Medicine, Seattle, Washington

*Department of Global Health Curriculum*

Advisor and contributor 2014 – 2019  
Global Perspectives in Reproductive Health  
Graduate: GH 590/Undergraduate: GH 490  
University of Washington School of Medicine, Seattle, Washington

Formal Teaching of Residents

Harborview Resident Lecture Series 2006 – 2010  
Lectures for residents and medical students: Contraceptive Overview, Intrauterine  
Contraception, Surgical and Medical Abortion, Management of First Trimester Loss  
Harborview Medical Center, Seattle, Washington

Resident Didactic Sessions 2007 – present

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## Yearly:

1. Values Clarification Exercise/Professionalism in Medicine: Exploring how to provide medical care in the face of personal judgements/differences of opinion
2. Papaya Workshop: Uterine aspiration simulation
3. IUD insertion training: simulation on a plastic uterine model
4. Nexplanon insertion and removal training: simulation on fake arms

## Every other year:

5. Contraceptive Conundrums: Challenging cases for contraceptive management.
6. Hormonal Contraception Overview
7. Long Acting Reversible Contraception
8. Medical Abortion
9. First and Second Trimester Abortion
10. Miscarriage Management

Faculty, Staff and Resident Teaching

Nexplanon Training: 2007 - present  
Instruction on placement and removal of implantable contraception (Annual sessions)

International Teaching

Immediate Postpartum IUD February 2009  
Insertion Training for Midwives and Ob/Gyns  
University Teaching Hospital, Lusaka, Zambia

Immediate Postpartum IUD November 2010  
Insertion Training for Midwives and Ob/Gyns  
Mulago National Referral Hospital, Kampala, Uganda

Other Medical Student Teaching

Medical Student Teaching 2006 – 2019  
Papaya Workshops: Instruction on uterine procedure skills  
University of Washington School of Medicine, Seattle, Washington

Medical Student Precepting 2007 – present  
Precept third year medical students during the Obstetrics and Gynecology clerkship  
University of Washington School of Medicine, Seattle, Washington

Medical Student Teaching 2007 – present  
Faculty Observer for the Pelvic Exam Module  
University of Washington School of Medicine, Seattle, Washington

Medical Student Core Lectures 2007 – 2014  
Contraception and abortion overview lecture to medical students on the Ob/Gyn rotation  
University of Washington School of Medicine, Seattle, Washington

Medical Student Teaching 2010 - 2019

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IUD Insertion Workshops: Instruction on insertion of all available methods of IUDs  
University of Washington School of Medicine, Seattle, Washington

Formal Mentoring*Faculty*

Alyssa Stephenson-Famy, MD 2011 – present  
Career Mentor, Clinician Educator Track

Elizabeth Micks, MD, MPH 2012 – 2022  
“Cervicovaginal immune response to vaginally-administered hormonal contraception”  
Career Mentor

Lyndsey Benson, MD, MS 2016 - present  
Early Pregnancy Loss Management in the Emergency Department  
Complex Family Planning Faculty, University of Washington, Seattle, Washington

Lauren Owens, MD, MPH 2022 - present  
Career Mentor, Clinician Educator Track, Associate Fellowship Director, CFP  
Complex Family Planning Faculty, University of Washington, Seattle, WA

*Graduate Students*

Kristen Upson, MPH 2007 -2009  
“Factors associated with contraceptive non-use among U.S. women ages 35-44 years at risk of unwanted pregnancy”. Published 2010  
Health Services Research, School of Public Health, University of Washington, Seattle, Washington

Blair Darney, MPH, PhD 2007 – 2012  
“The Family Medicine Residency Training Initiative in Miscarriage Management (RTI-MM): Impact on Practice in Washington State”. Published 2013  
Health Services Research, School of Public Health, University of Washington, Seattle, Washington

Lisa Callegari, MD 2011 – 2013  
“Factors associated with lack of effective contraception among obese women in the United States” Published 2014  
Health Services Research, School of Public Health, Health Services  
Obstetrics and Gynecology Faculty, University of Washington, Seattle, Washington

Kelly Gilmore 2012 – 2014  
“Providing long-acting reversible contraception services in Seattle school-based health centers: key themes for facilitating implementation” Published 2015  
Health Services Research, School of Public Health  
University of Washington, Seattle, Washington

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Catherine Wright, MPH, PhDc 2013 – present  
 “Pregnancy Loss and Cardiovascular Disease: Associations and Underlying Genetic Factors”.  
 PhD Program in Epidemiology, School of Public Health,  
 University of Washington, Seattle, Washington

Alison Ojanen-Goldsmith, MPH, MSW 2013 – present  
 “Beyond the Clinic: Preferences, Motivations and Experiences with Alternative Abortion Care”.  
 Manuscript preparation in process  
 Health Services Research, School of Public Health  
 University of Washington, Seattle, Washington.

Robin Supplee, ARNP, CNM, MPH 2015 – 2018  
 “Influence of Interdepartmental Training on the Practice of Miscarriage Management”  
 Manuscript preparation in process  
 Health Services Research, School of Public Health  
 University of Washington, Seattle, Washington

Catherine Henley, MPH, PhDc 2019 - 2022  
 “Contraceptive Use and Associated Sexual Behaviors Among Latina Adolescents Aged 18-19 in  
 the United States”  
 PhD Program in Epidemiology, School of Public Health,  
 University of Washington, Seattle, Washington

Genevieve Taylor, MPH 2020 - 2021  
 “ COVID-19 and Sexual and Reproductive Health Services in King County, Washington”  
 MPH Program in Epidemiology, school of Public Health  
 University of Washington, Seattle, Washington

*Fellows*

Annie Hoopes 2012 – 2015  
 “Knowledge and Acceptability of Long-Acting Reversible Contraception Among Adolescent  
 Women Receiving School-Based Primary Care Services” Published 2016  
 Health Services Research, School of Public Health  
 Adolescent Medicine Fellow, University of Washington, Seattle, Washington

Lyndsey Benson, MD, MS 2014 - 2016  
 “Heterosexual Anal Intercourse: Perception and Practices” Manuscript published  
 Family Planning Fellow, University of Washington, Seattle, Washington

Liz Harrington, MD, MPH 2015 – 2018  
 “Mobile phone SMS dialogue with women and their male partners (Mobile WACH XY) and  
 postpartum contraceptive uptake in Kenya: A randomized controlled trial”  
 Family Planning Fellow, University of Washington, Seattle, Washington

Lauren Owens, MD, MPH 2016 - 2018  
 “Understanding and meeting family planning needs of women who inject drugs”  
 Family Planning Fellow, University of Washington, Seattle, Washington

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Rebecca Taub, MD, MPH 2017 - 2019  
 “The effects of testosterone on ovulatory function in transmasculine individuals”  
 Family Planning Fellow, University of Washington, Seattle, Washington

Aishat Olatunde, MD, MS 2019 - 2021  
 “Comprehensive Early Pregnancy Loss Management in the Emergency Department”  
 Complex Family Planning Fellow, University of Washington, Seattle, Washington

Ferid Abbas Abubeker, MD MPH 2019 - 2021  
 “Medical termination for pregnancy in early first trimester ( $\leq$  63 days) using combination of mifepristone and misoprostol or misoprostol alone: a systematic review”  
 Family Planning Fellow, St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia

Tesfaye Hurisa Tufa, MD, MPH 2019 - 2021  
 “Drugs used to induce fetal demise prior to an abortion: a systematic review”  
 Family Planning Fellow, St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia

Lemi Tolu, MD, MPH 2019 - 2021  
 “Intra-cardiac lidocaine administration to induce fetal demise before late second-trimester abortion: Retrospective review”  
 Family Planning Fellow, St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia

Mekdes Daba Feyssa, MD, MPH 2019 - present  
 “COVID-19 and pregnancy: Information for health professionals”  
 Family Planning Fellow, St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia

Abraham Fessehaye 2020 - present  
 “Foley catheter for cervical preparation prior to second trimester dilation and evacuation: a supply-based alternative for surgical abortion”  
 Family Planning Fellow, St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia

Jennifer Chin, MD, MS 2020 - 2022  
 “Ketamine versus fentanyl for surgical abortions: a randomized noninferiority trial”  
 Complex Family Planning Fellow, University of Washington, Seattle, Washington

Alexandria Wells, MD, MBs 2022 - present  
 “Opinions and Usage of Family Planning Methods Pre and Post Dobbs”  
 Complex Family Planning Fellow, University of Washington, Seattle, Washington

***Residents***

Olivia Sementi 2008 - 2011  
 “Evidence-Based Selection of Candidates for the Levonorgestrel Intrauterine Device (IUD)”  
 Published 2014  
 Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Anna Altshuler, MD 2009 – 2013

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“How We Form Beliefs About Abortion: Social Media-Based Online Survey”

Published 2014

Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Carly Ingalls, MD

2013 – 2016

“Is Obesity an Independent Risk Factor for Abortion Complications?” Published 2016

Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Jordie Stevens, MD

2013 – 2020

“Leukocytosis, Fever and Bacteremia During Cervical Preparation with Osmotic Dilators for Dilation and Evacuation” Manuscript accepted for publication 2020

Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Kavita Vinekar, MD

2014 - 2019

“Differences in estimated blood loss with use of general anesthesia versus monitored anesthesia care for dilation and evacuation procedures” Manuscript submitted

Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Carlie Field, MD

2015 – 2019

“Simulation training in intrauterine contraception during pre-clinical years of medical school: A hands-on approach to improve awareness, enhance skills, and promote interest”

Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Kristin Lilja

2016 – 2019

“Urban versus rural access to emergency contraception in Washington”

Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Emily Unger

2019 - 2022

“Guidelines for Medication and Surgical Abortion in the First and Second trimester

Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Lauren MacNeill

2020 - present

“Abortion Training at the University of Washington OBGYN Residency Program: Resident Perspectives and Program Challenges”

Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

*Medical Students*

Tiana Nizamic

2012 - 2015

“Use of the Levonorgestrel-Releasing Intrauterine System in Transplant Patients”

Published 2014

University of Washington Medical School, Seattle, Washington

Malica Mantrala

2012 – 2015

“Safety of the Levonorgestrel Intrauterine System for Adolescents with Developmental Disabilities” Published 2014

University of Washington Medical School, Seattle, Washington



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Quyen Vu 2013 – 2016  
 “Efficacy and Safety of Long-Acting Reversible Contraception in Women With Cardiovascular Conditions” Published 2016  
 University of Washington Medical School, Seattle, Washington

Benjamin Lang 2014 – 2017  
 “Use of the levonorgestrel intrauterine device in women with type II diabetes mellitus  
 University of Washington Medical School, Seattle, Washington

Other Mentorship Activities

Faculty mentor for Medical Students for Choice 2006 - 2018  
 Faculty mentor for OBGYN Interest Group 2008 - 2019  
 American Medical Student Association 2021-present  
 Reproductive Health Mentor

**EDITORIAL ACTIVITIES**

Ad hoc reviewer for Ongoing  
*Archives of Gynecology and Obstetrics*  
*American Journal of Obstetrics and Gynecology*  
*Contraception*  
*European Journal of Public Health*  
*Global Health: Science and Practice Journal*  
*International Journal of Gynecology and Obstetrics*  
*Jama – Archives*  
*Journal of Adolescent Health*  
*Journal of Women’s Health*  
*Medical Decision Making*  
*Obstetrics and Gynecology*  
*Perspectives in Sexual and Reproductive Health*

**SPECIAL NATIONAL RESPONSIBILITIES**

Medical Students for Choice 1996 – 1998  
 Chapter Founder and President; University of Texas Southwestern Medical School  
 Medical Students for Choice 1999 – 2000  
 Regional Coordinator; Texas, Oklahoma and Louisiana  
 ACOG: Junior Fellow Vice-Chair and Chair, Vermont Section 2001 – 2003  
 ACOG: Junior Fellow Vice-Chair and Chair, District I 2003 – 2004

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ACOG: Committee on Gynecologic Practice	2004 – 2006
ACOG: CREOG Education Committee	2007 – 2010
CDC: Working Group: Selected Practice Recommendations for Contraception Use	2010 – 2013
CDC: Working Group: Updating the Medical Eligibility Criteria for Contraception Use and the Selected Practice Recommendations for Contraception Use	2015 – 2016
ACOG: Committee on Health Care for Underserved Women	2011 – 2018
Vice-Chair of the Committee	2014 – 2016
Chair of the Committee	2016 – 2018
National Abortion Federation: Member, Board of Directors	2017 – present
Chair, Committee on Clinical and Procedural Guidelines	2018 - present
ACOG: Scientific Co-Chair, District VIII and IX Annual District Meeting Planned the meeting, October 4-6, 2019, Maui, Hawaii.	2017-2018
ACOG: Abortion Access and Training Working Group Co-chair	2019 - current
ACOG: Secretary, District VIII	2022 - current
Society of Family Planning Member, Clinical Affairs Subcommittee	2019 - 2022
Write and/or review clinical guidelines on family planning topics	
Member, Education Committee	2022 - current
Write items for question bank for preparation for written boards	
Curate Complex Family Planning (CFP) fellowship curriculum	
Create/collate educational materials for CFP curriculum	

**SPECIAL LOCAL RESPONSIBILITIES**

ACOG:	
Secretary, District VIII, Washington Section	2009 – 2012
Treasurer, District VIII, Washington Section	2012 - 2013
Young Physician at Large for District VIII	2013 – 2015
Vice Chair, District VIII, Washington Section	2013 – 2016
Chair, District VIII, Washington Section	2016 - 2019
Legislative Chair, Washington Section	2019 - 2021
University of Washington Department of OBGYN Co-director of the Clinician Educators Working Group	2012 – present
Washington State Hospital Association	2013 - 2014

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Safe Deliveries Roadmap Postpartum Advisory Group: Member  
 Safe Deliveries Roadmap Prepregnancy Advisory Group: Member  
 Safe Deliveries Roadmap Steering Committee: Member

University of Washington Faculty Council on Women in Academia	
Member	2014 – 2016
Vice Chair	2016 - 2019

Center for Leadership and Innovation in Medical Education (CLIME)	2015 – 2019
Co-lead, Membership Core	

Seattle King County Public Health	2016 – 2019
Family Planning Access and Quality Committee: Member	

Washington State Department of Health	2017 - 2020
Maternal Mortality Review Panel: Member	

Upstream USA	2018 - present
Washington Advisory Committee Member	

University of Washington Medical Center	2021 - present
Council on Appointments and Promotion	

**SPECIAL INTERNATIONAL RESPONSIBILITIES**

Evaluation of Family Planning Services: Focus on IUD insertion	January 2010
Nepal	

Evaluation of Family Planning Services: Focus on Implant insertion	November 2012
Zimbabwe	

Population Services International	May 2014
Evaluation of Family Planning Services: Focus on Implant insertion	
Zambia	

Population Services International	May 2015
Evaluation of Family Planning Services: Focus on LARC	
Pakistan	

St. Paul Institute for Reproductive Health and Rights (SPIRHR)	2021 - present
Advisor to the Board (Cannot serve on Board as non-Ethiopian)	
Help guide clinical, research, advocacy and educational efforts in Ethiopia	

**FUNDING HISTORY**Current

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*Strengthening the Family Planning and Abortion Training Program at St. Paul Hospital and Millennium Medical College (Prager)*

Anonymous Foundation  
Principal Investigator  
2020 - 2023 (Extension)  
\$202,602

*Training, Education, and Advocacy in Miscarriage Management (Prager)*

Washington State Department of Health, HED23409-1  
Principal Investigator  
07/01/2021 – 06/30/2023  
\$193,648

*Fellowship in Family Planning (Prager)*

Anonymous Foundation  
Director  
07/01/2014 – 06/30/2023 (Extension)  
\$2,337,851

Past

*HPV status of LEEP negative specimens (Wegner)*

University Health Center College of Medicine Research Committee  
Co-Investigator  
2003 – 2004  
\$9,000

*Immediate Initiation of Oral Contraceptive Pills after Therapeutic Abortion, Immediate Initiation of Transdermal Hormonal Contraception after Therapeutic Abortion (Prager)*

Anonymous Foundation  
Principal Investigator  
2005 – 2008  
\$70,440

*Comparison of Oral and Patch Hormonal Contraception on Metabolic, Thrombotic and Vascular Response (Knopp)*

Ortho McNeil Pharmaceuticals, NCT0043997  
Co-Investigator  
2006 – 2010  
\$761,500

*Ryan Residency Training Program in Family Planning (Prager)*

Anonymous Foundation  
Principal Investigator  
2006 – 2009  
\$869,953

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*University of Washington, Family Medicine Training, Resident Training Initiative in Miscarriage Management Program (Prager)*

Washington State Department of Health, N17270

Principal Investigator

2008 – 2009

\$448,071

*Miscarriage Management Training Initiative (Prager)*

Abortion Access Project

Principal Investigator

2009 – 2013

\$777,648

*Interferon Pathway Targeting by Depo-Provera in Women (Prager)*

Society of Family Planning, SFP5-13

Principal Investigator

2011 – 2013 (Extension)

\$12,497

*Formation of Abortion Attitudes (Prager)*

Society of Family Planning Research Fund, SFPRF6 – T8

Principal Investigator

2012 – 2013

\$5,000

*Early Pregnancy Loss (Steinauer)*

University of California, San Francisco

Co-Investigator

2015 - 2016

\$17,106

*Nanofiber MPT Development (Woodrow)*

Bill and Melinda Gates Foundation, 66-9897

Co-Investigator

2015 - 2017

*Injectable Microspheres for fertility Regulation by Endocrine Enhancement (iMFree): A Longer-Acting Injectable Contraceptive (Ratner)*

FHI 360, OPP1055878 AM02

Co-Investigator

2016 - 2017

\$559,003

*Training, Education, and Advocacy in Miscarriage Management (Prager)*

Washington State Department of Health, N18447, HED23409

Principal Investigator

07/01/2010 – 06/30/2021 (Extension)

\$1,070,308

Last Updated: 2/14/2023

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*Effects of contraceptive ring on vaginal microbiota, HIV shedding & local immunity (Marrazzo)*

National Institute of Health, 1 R01 HD077872-01

Co-Investigator

2014 – 2019

\$376,729

*Training, Education and Advocacy in Miscarriage Management (Prager)*

Anonymous Foundation

Principal Investigator

2013 – 2021 (Extension)

\$1,237,250

*Exploring stakeholder perspectives and creating community dialogue on the practice and security of community-based and self-provided abortion care: A community-based participatory research project (Prager, Ojanen-Goldsmith)*

Society of Family Planning Research Fund, A122100

Co-Principal Investigator

2017 – 2021

\$150,000

**BIBLIOGRAPHY**Peer Reviewed Journal Articles

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2. **Prager SW**, Steinauer JE, Foster SD, Darney PD, Drey EA. Risk factors for repeat elective abortion. *Am J Obstet Gynecol* 2007; 197:575.e1-575.e6. PMID: 17904511.
3. **Prager SW**, Oyer DJ. Second-trimester surgical abortion. *Clin Obstet Gynecol*. 2009 Jun;52(2):179-87. doi: 10.1097/GRF.0b013e3181a2b43a. Review. PMID: 19407524.
4. Lyus R, Lohr P, **Prager S**; Board of the Society of Family Planning. Use of Mirena LNG-IUS and ParaGard CuT380A intrauterine devices in nulliparous women. *Contraception*, May 2010; 81(5): 367- 371. PMID: 20399942.
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7. Lyus R, Lohr P, **Prager S**. The Dalkon Shield and pelvic infection. *Contraception*, July, 2011; 84(1): 108-109.
8. **Prager S**, Gupta P, Chilambwe J, Vwalika B, Neukom J, Siamwanza N, Eber M, Blumenthal PD. Feasibility of training Zambian nurse-midwives to perform postplacental and postpartum insertions of intrauterine devices. *International Journal of Obstetrics and Gynecology*; 2012 Jun;117(3):243-7. PMID: 22445950.

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12. Darney BGD, VanDerhei D, Weaver MR, Stevens NG, **Prager SW**. "We have to what?": Lessons learned about engaging support staff in an interprofessional intervention to implement MVA for management of spontaneous abortion. *Contraception.* 2013 Aug;88: 221-225. PMID: PMC4085572.
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14. Steinauer JE, Sokoloff A, Roberts EM, Drey EA, Dehlendorf CE, **Prager SW**. Immediate versus delayed initiation of the contraceptive patch after abortion: a randomized trial. *Contraception.* 2014 Jan;89(1):42-7. PMID: 24176251.
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17. Amies Oelschlager AME, Micks EA, Debiec KE, Nizamic T, Mantrala MD, **Prager SW**. Long Acting Reversible Contraception in Adolescents with Cardiovascular Conditions. *J Ped and Adolesc Gynecol* (2014) Dec(6):353-5. PMID: 25256877.
18. **Prager S**. Committee on Healthcare for Underserved Women. Committee Opinion No. 615. Access to contraception. *Obstet Gynecol* 2015 Jan;125(1):250–5. PMID: 25560140
19. Altshuler AL, Gerns Storey HL, **Prager SW**. Exploring abortion attitudes of US adolescents and young adults using social media. *Contraception.* 2015 Mar;91(3):226-33. PMID: 25537853.
20. **Prager SW**, Dalton VK, Allen RH. Committee on Practice Bulletins – Gynecology. ACOG Practice Bulletin no. 150: Early Pregnancy Loss. *Obstet Gynecol.* 2015 May;125:1258–67. PMID: 25932865
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28. Lohr PA, Lyus R, **Prager S**. Use of intrauterine devices in nulliparous women. *Contraception*. 2017 June;95(6):529-537. PMID: 27591814
29. **Prager S**. Committee on Health Care for Underserved Women. Committee Opinion No 707: Access to Emergency Contraception. *Obstet Gynecol*. 2017 Jul;130(1): e48-e52. PMID: 28644339
30. Kelly E Quinley, MD, Deborah Chong, MD, **Sarah Prager, MD MAS**, Charlotte Page Wills MD, Arun Nagdev, MD, Sara Kennedy, MD MPH. Manual uterine aspiration: adding to the emergency physician stabilization toolkit. *Annals of Emergency Medicine*. 2017 Dec 13. PMID: 29248332.
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  53. Mark A, Roberts R, Foster AM, **Prager SW**, Ryan R, Winikoff B. "Who is driving you home today?" Escort policy as a barrier to abortion access. *Contraception*. 2022 Jan 11:S0010-7824(21)00498-4. doi: 10.1016/j.contraception.2021.12.012. PMID: 35031304.
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  55. Erin E McCoy, Amanda KH Weidner, Lyndsey S Benson, Blair G Darney & **Sarah W Prager**. (2022) Practice change following an interdepartmental training on early pregnancy loss management in the emergency department. *Cogent Public Health*, 9:1, 2052402, DOI: 10.1080/27707571.2022.2052402. <https://doi.org/10.1080/27707571.2022.2052402>
  56. Sarah Horvath MD, MSHP, Vinita Goyal MD, MPH, Sarah Traxler MD, MSHP, **Sarah Prager MD, MAS**. Society of Family Planning committee consensus on Rh testing in early pregnancy, *Contraception* (2022), doi: <https://doi.org/10.1016/j.contraception.2022.07.002>
  57. Jennifer Chin, MD, Madeline McGrath, BA, Erica Lokken, PhD, Carlos Delgado Upegui, MD, **Sarah Prager, MD, MAS**, Elizabeth Micks, MD, MPH. Ketamine Compared With Fentanyl for Surgical Abortion: A Randomized Controlled Trial. *Obstet Gynecol* 2022;00:1-9. DOI: 10.1097/ACOG.0000000000004903
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**Book Chapters**

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5. David Turok and **Sarah Prager**. Academic Family Planning and Sexual and Reproductive Health Collaborations: Training and Advocacy with Community Partners. In: Advancing Women's Health Through Medical Education: A Systems Approach in Family Planning and Abortion. Cambridge University Press. 2021. DOI: 10.1017/9781108884709

Published Books, Videos, Software, etc.

**Prager S.** (Faculty Collaborator). Inserting Long Acting Reversible Contraception (LARC) Immediately After Childbirth. eLearning Course, Independent Study, 2014.  
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Other Publications

1. **Prager S**, Darney P. Can the levonorgestrel-releasing intrauterine system (Mirena®) be used in nulliparous women? Gynaecol Forum 2006; 11:7-9.
2. **Prager S**, There is no post-abortion syndrome. Guest Columnist, Seattle Post-Intelligencer July 9, 2007.
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4. CREOG Educational Objectives Ninth Edition (Co-authored with CREOG Education Committee) 2010.
5. Micks E, **Prager S**. Plan A: postabortion contraception. Clin Obstet Gynecol. 2014 Dec;57(4):751-62. PMID: 25254920.
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8. Alice Mark, Angel M. Foster, Daniel Grossman, **Sarah W. Prager**, Matthew Reeves, Cristina Villarreal Velásquez, Beverly Winikoff. Foregoing Rh testing and anti-D immunoglobulin for women presenting for early abortion: a recommendation from the National Abortion Federation's Clinical Policies Committee. Contraception. May 2019 Volume 99, Issue 5, Pages 265–266. DOI: <https://doi.org/10.1016/j.contraception.2019.02.008>
9. Mahlet Yigeremu, **Sarah W. Prager**, Sofanit Haile. Maintaining SRH Services during the COVID-19 Pandemic. COVID-19 Pregnancy and Women's Health for Health Care Professionals. May 06, 2020, Ethiopian Society of Obstetricians and Gynecologists. [http://www.esog-eth.org/images/Update-2020/COVID-19\\_FOR\\_PROVIDERS-ESOG\\_VERSION\\_01\\_1.pdf](http://www.esog-eth.org/images/Update-2020/COVID-19_FOR_PROVIDERS-ESOG_VERSION_01_1.pdf).
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15. **Prager S**, Micks E, Dalton VK. Pregnancy loss (miscarriage): Clinical presentations, diagnosis, and initial evaluation. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com>. Last updated: July 9, 2021. Accessed October. 6, 2021.
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19. **Sarah Prager**. Managing Miscarriage in the Emergency Department and Beyond - In any medical setting, here are a few ways to provide support. MedPage Today. February 14, 2023. <https://www.medpagetoday.com/opinion/second-opinions/103099?tw=no>

Abstracts

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## **INVITED LECTURES/PRESENTATIONS**

UVM/Fletcher Allen Health Care: "*The History of Abortion*"  
Burlington, VT, May 25, 2004

Women's Health Elective: "Medical and Surgical Abortion"  
San Francisco, CA, November 2, 2004

ACOG Annual Clinical Meeting: "*Prophylactic Antibiotics for Abortion*"  
San Francisco, CA, May 11, 2005

UCSF/SFGH Faculty Seminar: "*The History of Abortion*"  
San Francisco, California, August 24, 2005

South Bay Mid-Level Practitioner Continuing Medical Education  
Sponsored by FEI Women's Health: "*Intrauterine Contraception (IUC): A Liberal's View*"  
San Mateo, CA, September 22, 2005

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Physicians for Reproductive Choice and Health: *Round table presentation regarding Proposition 73*, San Francisco, CA, September 29, 2005

CNM group: *"Contraceptive use in Women with Medical Conditions"*  
San Francisco, CA, November 17, 2005

University of California, Berkeley; Tang Health Center: *"Introduction to the IUD for Primary Care Providers"*, Berkeley, California, April 27, 2006

ACOG Annual Clinical Meeting: *"Intrauterine Contraception in Nulliparous Women"*  
Washington, DC, May 9, 2006

Instituto Nacional de Salud Publica, Graduate Program in Reproductive Health  
*"Overview of Intrauterine Contraception"*, Cuernavaca, Mexico, May 24, 2006

Association of Reproductive Health Professionals (Co-Presented with Dr. Eleanor Drey)  
*"A New Look at Post Abortion IUD Insertion"*, La Jolla, CA, September 8, 2006

Medical Students for Choice/Law Students for Choice: *"Medical Perspectives on the Federal (Partial Birth) Abortion Ban"*, Seattle, WA, November 7, 2006

STD Update Course: *"Contraceptive Update"*; Seattle, WA, February 6, 2007

Workshop on Psychosocial Issues in Abortion Care: *"Emotional issues in doing and teaching abortion"*, San Francisco, CA, February 18, 2007

Women's Healthcare Update: *"Contraceptive Implant Overview and Principles of IUD Insertion"*, Seattle, WA, March 2, 2007

Medical Students for Choice Annual Meeting: *"New Frontiers in Contraception"*  
St. Petersburg, FL, March 24, 2007

Medical Students for Choice Annual Meeting: *"The Pro-Choice Medical Student's Guide to Applying for Residency"*, St. Petersburg, FL, March 25, 2007

University of Washington School of Medicine-Ob/Gyn Faculty Development Workshop  
*"Contraception Update – New Methods and New Thoughts on Old Methods"*  
Seattle, WA, April 20, 2007

Family Planning Fellowship Annual Meeting: Promoting IUC Use in Clinical Practice  
*"Intrauterine Contraception in Adolescent and Nulliparous Women"*  
San Diego, CA, May 4, 2007

Family Planning Fellowship Annual Meeting: Promoting IUC Use in Clinical Practice  
*"Intrauterine Contraception: Patient Selection, Preparation and Follow-up"*  
San Diego, CA, May 4, 2007

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ACOG Annual Clinical Meeting: *“Non-Contraceptive Uses of the Levonorgestrel Intrauterine System”*, San Diego, CA, May 7, 2007

ACOG Annual Clinical Meeting: *“What Really Is the Deal with Infection and Medical Abortion?”*, San Diego, CA, May 8, 2007

Washington State Association of Abortion Providers: *“Misoprostol: a Review of the Literature”*, Seattle, WA, May 17, 2007

Public Health Seattle and King County: Sexually Transmitted Disease Conference  
*“Contraception Update”*, Seattle, WA, May 22, 2007

University of Washington Cardiac Care Clinic: *“Contraception for the Cardiac Patient”*  
Seattle, WA, May 24, 2007

University of Vermont/Fletcher Allen Health Care, Department of Obstetrics and Gynecology  
Grand Rounds: *“This is not your mother’s IUD: an update on intrauterine contraception”*,  
Burlington, VT, September 4, 2007

University of Washington School of Medicine  
35<sup>th</sup> Annual Advances in Family Practice and Primary Care  
*“Treatment Options for First Trimester Loss”*, Seattle, WA, September 11, 2007

University of Washington School of Medicine, Department of Obstetrics and Gynecology Grand  
Rounds: *“This is not your mother’s IUD: an update on intrauterine contraception”*, Seattle, WA,  
September 19, 2007

National Abortion Federation Risk Management Seminar, Panel discussion on second trimester  
provision and training; Victoria, Canada, October 16, 2007

Washington State Academy of Physician Assistants (WAPA)  
19<sup>th</sup> Annual Recertification Review Course Winter conference and AAPA Western Regional  
Meeting: IUD Insertion Workshop; Seattle, WA, January 29, 2008

19<sup>th</sup> Annual Recertification Review Course Winter conference and AAPA Western Regional  
Meeting: *“Contraceptive Review and Update”*, Seattle, WA, January 29, 2008

David Geffen School of Medicine at the University of California, Los Angeles  
Department of Obstetrics and Gynecology Grand Rounds: *“This is not your mother’s IUD: an  
update on intrauterine contraception”*, Los Angeles, CA, February 1, 2008  
Washington State Academy of Physician Assistants (WAPA)

David Geffen School of Medicine at the University of California, Los Angeles  
Department of Obstetrics and Gynecology Resident Didactics:  
*“Contraceptive Conundrums”*, Los Angeles, CA, February 1, 2008

Workshop on Psychosocial Issues in Abortion Care, Panel Discussion: Your Role as a Family  
Planning Specialist; San Francisco, CA, February 24, 2008

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University of Washington Department of Family Medicine Faculty Development  
Values Clarification Workshop on Abortion; Seattle, WA, February 27, 2008

Women's Healthcare Update, University of Washington CME:  
*"What's New in Contraception"*, Seattle, WA, March 7, 2008

Swedish Family Medicine, Cherry Hill Campus, Department of Family Medicine Resident  
Didactics: Values Clarification Workshop on Abortion, Seattle, WA, March 11, 2008

Center for Health Training, 37<sup>th</sup> Annual Regional Reproductive Health (RH) 2008 Conference:  
*"This Is Not Your Mother's IUD: An Update on Intrauterine Contraception"*  
Bellevue, WA, March 19, 2008

Center for Health Training, 37<sup>th</sup> Annual Regional Reproductive Health (RH) 2008 Conference:  
*"Menstrual Irregularities and Abnormal Bleeding"*  
Bellevue, WA, March 21, 2008

University of Washington School of Pharmacy: *"Non-Oral Methods of Hormonal Contraception"*,  
Seattle, WA, April 22, 2008

University of Washington School of Medicine, Department of Family Medicine Faculty Didactics:  
*"Medical Abortion: protocols, complications and management"*; *"Hands-on practicum: manual vacuum aspiration"*; *"Surgical Abortion Techniques, complications and management"*, Seattle, WA, April 24, 2008

ACOG Annual Clinical Meeting: *"Non-Contraceptive Uses and Benefits of the Levonorgestrel Intrauterine System"*, New Orleans, LA, May 6, 2008

University of Washington School of Medicine, Department of Family Medicine Faculty Didactics:  
*"Contraception Update"*; *"Ultrasound Techniques in Early Abortion"*; *"Options Counseling"*; *"How To Teach Abortion"*, Seattle, WA, June 12, 2008

University of Washington School of Medicine, Department of Adolescent Medicine  
*"Contraceptive Update"*, Seattle, Washington, July 2, 2008

University of Washington School of Medicine, Department of Psychiatry  
*"Contraception for the Psychiatrist"*, Seattle, Washington, September 4, 2008

University of Washington School of Medicine, 36<sup>th</sup> Annual Advances in Family Practice and Primary Care: *"What's new in Contraception?"*, Seattle, WA, September 11, 2008

Family Medicine Residency Network, Resident Training Initiative in Miscarriage Management (RTI-MM) Program: *"Management of Early Pregnancy Loss (EPL)"*,  
*"Surgical Management of EPL"*, *"Papaya Workshop"*, Seattle, WA, September 29, 2008

Washington State Obstetrics Association Annual Meeting  
*"This Is Not Your Mother's IUD"*, Seattle, WA, December 6, 2008

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Washington State Academy of Physician Assistants (WAPA)  
20<sup>th</sup> Annual Recertification Review Course and Winter conference  
*"Contraceptive Review and Update"*. Seattle, WA, January 27, 2009

Group Health Cooperative CME, Obstetrics and Gynecology for Primary Care  
*"IUD Updates", "Miscarriage Management"*, Seattle, WA, February 27, 2009

University of Washington, Hall Health Student Health Center  
*"What's New in Contraception"*, Seattle, WA, March 10, 2009

Swedish Family Medicine, Cherry Hill Campus, Department of Family Medicine Resident  
Didactics: Values Clarification Workshop on Abortion, Seattle, WA, March 10, 2009

Group Health Cooperative Faculty Didactic: *"First Trimester Abortion Care"*  
Seattle, WA, March 10, 2009

Women's Healthcare Update, University of Washington CME  
*"Contraception for Menstrual Suppression: New Applications of an Old Idea"*  
Seattle, WA, March 20, 2009

Workshop on Psychosocial Issues in Abortion Care, Panel Discussion: Promoting Psychosocial  
Wellbeing, San Francisco, CA, April 4, 2009

Yakima Valley Memorial Hospital, Department of Obstetrics and Gynecology  
*"What's New in Contraception"*, Yakima, WA, April 24, 2009

ACOG Annual Clinical Meeting: *"Why Go To the OR? Outpatient management of Early  
Pregnancy Failure"*, Chicago, IL, May 4, 2009

Diabetes in Pregnancy Study Group West Annual Meeting  
*"The Effects of Patch versus Oral Contraception on Lipoproteins and Coagulation Factors: a  
Randomized Crossover Study"*, Seattle, WA, May 16, 2009

Washington State Association of Abortion Providers: *"Medical Abortion Update"*  
Seattle, WA, May 20, 2009

University of Utah, Department of Obstetrics and Gynecology Grand Rounds  
*"Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss"*  
Salt Lake City, UT, August 20, 2009

Southwest Washington Hospital Center, Department of Obstetrics and Gynecology Grand  
Rounds: *"Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss"*,  
Vancouver, WA, September 9, 2009

Washington Hospital Center, Department of Obstetrics and Gynecology Grand Rounds  
*"Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss"*  
Washington, D.C., September 17, 2009

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University of California, Irvine Department of Obstetrics and Gynecology Grand Rounds  
*"Medical Abortion: Surgery Is Not the Only Option"*, Irvine, CA, October 2, 2009

University of Washington/Harborview Hospital, Department of Emergency Medicine Copass  
Rounds: *"Vaginal bleeding, pregnancy and other ob/gyn issues in the Emergency Room"*,  
Seattle, WA, October 13, 2009

Leadership Workshop 2009, Fellowship in Family Planning: *"Advocating for Change while  
Balancing Professional and Personal Needs"*, Chicago, IL, November 6, 2009

Washington Academy of Family Physicians, 60<sup>th</sup> Annual Scientific Assembly  
*"Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss"*  
*"Papaya Workshop – learning uterine aspiration with a manual vacuum aspirator on a papaya  
model"*, Cle Elum, WA, November 15, 2009

University of Washington Medical Center/Harborview Medical Center  
Sexually Transmitted Disease Program: *"Continuous Contraception and Contraception Update"*,  
Seattle, WA, December 29, 2009

University of Washington Law School, Disability Law Alliance Panel Discussion  
*"Selective Abortion on the basis of Disability"*, Seattle, WA, March 2, 2010

Women's Healthcare Update, University of Washington CME  
*"Contraception for the Medically Complex Patient"*, Seattle, WA, March 26, 2010

Center for Health Training, 39<sup>th</sup> Annual Regional Reproductive Health (RH) 2010 Conference:  
*"Forget about it! Long-Acting Reversible Contraception (LARC)"*  
Bellevue, WA, April 8, 2010

Society for Teachers of Family Medicine, Annual Spring Conference, 2010: *"Outpatient  
Miscarriage Management Should Be a Part of Every Resident's Medical Home"*  
With Dr. J. Mark Beard and Dr. Nancy Stevens, Vancouver, BC Canada, April 26, 2010

Infectious Disease Society of Obstetrics and Gynecology (IDSOG) Annual Scientific Meeting:  
*"Contemporary IUDs and Infection Risk"*  
Santa Fe, NM, August 5, 2010

University of Washington School of Medicine, 38<sup>th</sup> Annual Advances in Family Practice and  
Primary Care: *"Contraception for the Medically Complex Patient"*  
Seattle, WA, September 14, 2010

University of Washington School of Law: *"Federal Abortion Ban: Clinical Implications"*  
Seattle, WA, October 19, 2010

Cedars-Sinai Medical Center Department of Obstetrics and Gynecology, Grand Rounds:  
*"Contemporary IUDs and Infection Risk"*, Los Angeles, CA, January 26, 2011

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Women's Healthcare Update, University of Washington CME  
*"Contraception for the Medically Complex Patient"*, Seattle, WA, March 24, 2011

ACOG Annual Clinical Meeting: *"Why Wait? Immediate Post Partum IUD Insertion"*,  
Washington D.C., May 3, 2011

Association of Reproductive Health Professionals Annual Meeting: *"Evidence-based First  
Trimester Abortion Care"*, Las Vegas, NV, September 15, 2011

Association of Reproductive Health Professionals Annual Meeting: *"Report on the Resident  
Training Initiative in Miscarriage Management (RTI-MM): Systems Based Change on  
Clinic-Based Provision of Miscarriage Management"*, Las Vegas, NV, September 16, 2011

Seattle Gynecological Society Fall Assembly: *"What's New in Contraception"*, Seattle, WA,  
October 1, 2011

North American Forum on Family Planning: *"Around the World in 80 Days: Lessons learned in  
postpartum IUD trainings in the developing world"*, Washington, DC, October 24, 2011

North American Forum on Family Planning: *"Ensuring Broader Exposure to Uterine Evacuation  
Techniques"*, Washington, DC, October 24, 2011

Washington State Association of Abortion Providers: *"Evidence-based use of Long Acting  
Reversible Contraception (LARC)"*, Seattle, WA, November 9, 2011

Washington State Academy of Physician Assistants (WAPA)  
23<sup>th</sup> Annual Recertification Review Course and Winter conference  
*"Do Nothing, Do Something, Do Surgery: An Overview of Miscarriage Management"*. Seattle,  
WA, January 30, 2012

University of Nevada, Las Vegas: Grand Rounds and simulation courses  
*"Manual Vacuum Aspiration"*, *"Interval and Immediate Post Partum IUD insertion"*, *"Diaphragm  
Fitting"*. Las Vegas, Nevada, February 2, 2012

Center for Health Training, 41<sup>st</sup> Annual Regional Reproductive Health (RH) 2010 Conference:  
*"Case Management: Contraceptives for Women with Chronic Conditions"*, presented with Dr.  
Deborah Oyer, Portland, OR, March 21, 2012

Women's Healthcare Update, University of Washington CME  
*"What's New in Contraception and Family Planning"*, Seattle, WA, March 22, 2012

ACOG Annual Clinical Meeting: *"Surgical Miscarriage Management in the Office Setting"*, San  
Diego, CA, May 8, 2012

ACOG Annual Clinical Meeting: *"Medical management of spontaneous and elective abortion"*,  
San Diego, CA, May 8, 2012

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NeighborCare Grand Rounds: “*Early Pregnancy Loss and Manual Vacuum Evacuation*”, Seattle, WA, August 15, 2012

STI Conference: “*What’s New in Contraception*”, Boise, ID, September, 12, 2012

University of Washington Grand Rounds: “*Medical Abortion: everything you ever wanted to know but were afraid to ask*”, Seattle, WA, October 3, 2012.

International Federation of Obstetrics and Gynecology (FIGO), “*Expanding MVA training and competence in rural areas*” (panel discussion), Rome, Italy, October, 9, 2012.

International Federation of Obstetrics and Gynecology (FIGO), “*Around the world in 80 days: immediate postpartum IUD insertion*” (panel discussion), Rome, Italy, October, 10, 2012.

Washington State Academy of Physician Assistants (WAPA)  
24<sup>th</sup> Annual Recertification Review Course and Winter conference  
“*Do Something, Do Nothing, Do Surgery: An Overview of Miscarriage Management*”. Seattle, WA, January 28, 2013

STI Conference: “*What’s New in Contraception*”, Seattle, WA, January, 1, 2013

Current Concepts in Drug Therapy: “*Case Management: Contraceptives for Women with Chronic Conditions*”, Seattle, WA, March 7, 2013

Women’s Health Care Update: “*Case Management: Contraceptives for Women with Chronic Conditions*”, Seattle, WA, March 29, 2013

ACOG Annual Clinical Meeting: “*Medical management of spontaneous and elective abortion*”, New Orleans, LA, May 7, 2013

University of Hawaii Grand Rounds, “*Post Partum IUD insertions: a viable option*”, Honolulu, HI, June 26, 2013

Fellowship in Family Planning Global Health Placements Workshop, “*Making Global Health Relevant Domestically*”, October, 2013

University of Vermont Department of OBGYN Grand Rounds, “*Contraception for the medically complex patient*”, Burlington, VT, October, 22, 2013

STI Conference: “*Contraception Update*”, Seattle, WA, January, 29, 2014

Fellowship in Family Planning Annual Meeting: “*Controversies in Family Planning Panel Discussion*”, Chicago, IL, April 25, 2014

ACOG Annual Clinical Meeting: “*Medical management of spontaneous and elective abortion*”, Chicago, IL, April 28, 2014

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Women's Health Care Update: "*Medical Management Early Pregnancy Loss*", Seattle, WA, March 27, 2015

Madigan Department of OBGYN Grand Rounds, "*Medication management of spontaneous and elective abortion*", Lakewood, WA, April 1, 2015

ACOG Annual Clinical Meeting: "*Medical management of spontaneous and elective abortion*", San Francisco, CA, May 3, 2015

Peace Health Hospital Grand Rounds: "*Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss*", Bellingham, WA, May 13, 2015

Brown University Department of OBGYN Grant Rounds, "*Postpartum IUD insertions: a viable option*", Providence, RI, August 3, 2015.

Yakima Regional Hospital OBGYN Grand Rounds, "*Postpartum IUD insertions: a viable option*", September 25, 2015

FIGO, "*Outpatient management of early pregnancy loss (EPL) including incomplete abortion*", Vancouver, BC, Canada, October 8, 2015

Washington Women's Foundation Discovery Days, "*Family Planning Impacts on Maternal and Child Health*", Seattle, Washington, November 10, 2015

North American Forum of Family Planning, "Digital Learning for Early Pregnancy Loss Management", Chicago, IL, November 14, 2015

ACOG Annual Clinical Meeting: "*Medical management of spontaneous and elective abortion*", San Francisco, CA, May 17, 2016

ACOG Annual District Meeting, District XIII and XI: "*Rethinking the Well-Woman Exam*" Kona, Hawaii, September 24, 2016

ACOG Annual District Meeting, District XIII and XI: "*Opportunistic Salpingectomy versus Bilateral Tubal Ligation*". Kona, Hawaii, September 23, 2016

University of Texas, Southwestern, Department of OBGYN Grand Rounds: "*Contraception for the Medically Complicated Patient*". Dallas, TX, October 12, 2016

Washington State Obstetrics Association Annual Meeting: "*Everything You'd Ever Want to Know about Immediate Postpartum LARC Insertion*". Seattle, WA, December 1, 2016

Women's Health Care Update: "*Medical Abortion: An Effective, Non-Invasive Option*", Seattle, WA, March 24, 2017

ACOG Annual Clinical Meeting: "*Medical management of spontaneous and elective abortion*", San Diego, CA, May 8, 2017

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ACOG Annual District Meeting, District II: *"Management of Early Pregnancy Loss"*, Bermuda, October 6, 2017

National Abortion Federation Annual Meeting: *"Establishing Trans Health Services Workshop"*, Seattle, WA, April 21, 2018

National Abortion Federation Annual Meeting: *"The Future of Compassionate Abortion Care: Teaching Word Choice"*, Seattle, WA, April 23, 2018

National Abortion Federation Annual Meeting: *"The Human Right to Abortion: What it Means, and Why It Matters"*, Seattle, WA, April 23, 2018

ACOG Annual Clinical and Scientific Meeting: *"Medical management of spontaneous and elective abortion"*, Austin, TX, April 27, 2018

ACOG Annual Clinical and Scientific Meeting: *"Family Planning Update for the Comprehensive OB-GYN"*, Austin, TX, April 27, 2018

University of British Columbia: *"Professionalism and Conscientious Objection in Obstetrics and Gynecology"*, Vancouver, BC, Canada, July 20, 2018

FIGO: *"Abortion Technology Workshop"*, Rio de Janeiro, Brazil, October 14, 2018

FIGO: *"Second Trimester Abortion"*, Rio de Janeiro, Brazil, October 18, 2018

North American Forum on Family Planning: *"Yes We Can! Interdisciplinary management of early pregnancy loss in the emergency department"*, New Orleans, LA, October, 21, 2018

Ethiopian Society of Obstetricians and Gynecologists Annual Meeting: *"Updates on the Management of Contraception for Women with Medical Conditions"*, Addis Ababa, Ethiopia, February 4, 2019

Women's Healthcare Update: *"Making Sense of Complex Contraception"*, Seattle, WA, March 28, 2019

ACOG Annual Clinical and Scientific Meeting: *"Evidence-based management of second trimester fetal loss"*, Nashville, TN, May 4, 2019

ACOG Annual Clinical and Scientific Meeting: *"Medical management of spontaneous and elective abortion"*, Nashville, TN, May 5, 2019

Saint Paul's Hospital Millennium Medical College Center of Excellence in Reproductive Health: 1st National Symposium on Reproductive Health. *"Evidence-Based Medical Management of Abortion in the Second Trimester: A Protocol for St. Paul and Ethiopia"*. Addis Ababa, Ethiopia, November 1, 2019

Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting 2020: *"Male Contraceptives: Current and Future Approaches"*, Addis Ababa, Ethiopia, February 15, 2020.

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Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting 2020: *“Second Trimester Abortion Care: Current Status and Approaches”*, Addis Ababa, Ethiopia, February 16, 2020.

Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting: Plenary Session: *“Emerging Issues in Sexual and Reproductive Health and Rights (SRHR): Opportunities and Challenges”*, Addis Ababa, Ethiopia, February 17, 2020.

National Remote OBGYN Resident Didactics: *“Medication management of abortion and pregnancy loss”*. 5/19/2020.

<https://obgyn.ucsf.edu/residency-program/national-curriculum>.

Contraceptive Technology: *“Management of first trimester abortion and early pregnancy loss”*. 9/23/2020.

Contraceptive Technology: *“Medication management of abortion and pregnancy loss”*. 9/25/2020.

Society of Family Planning: *“Early Pregnancy Assessment Clinics: let’s standardize algorithms, combine with family planning, and overcome disparities”*. 10/10/2020.

ASRM: *“A Team Approach to Providing Early Pregnancy Loss Care in the Emergency Department and Outpatient Settings”*. 10/17/2020

St. Paul’s Institute for Reproductive Health Research, Second Annual Conference: *“Provision of abortion and family planning services amid COVID-19: challenges and mitigations”*. 11/14/2020.

ASRM Live Zoom Q&A: *“A Team Approach to Providing Early Pregnancy Loss Care in the Emergency Department and Outpatient Settings”*. 12/05/2020

Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting 2021: *“Update on Hormonal Contraception”*, Addis Ababa, Ethiopia, February 15, 2021.

Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting 2021: *“Updates on Second Trimester Surgical Abortion Care”*, Addis Ababa, Ethiopia, February 15, 2021.

MedStar Washington Hospital Center/MedStar Georgetown University Hospital Virtual Grand Rounds: *“Abortion and Abortion Training in Ethiopia”*, Washington, D.C., March 11, 2021.

University of Washington Medical School Educational Series: *“Let’s talk About: Reproductive Health and Rights”*, Seattle, WA, March 31, 2021.

John Gibbons, Jr., MD, Medical Student Lecture: *OB-GYN as a Career*. ACOG Annual Clinical Meeting. April 23, 2021. Virtual meeting.

University of Kansas Medical Center Grand Rounds: *Medication Management of Pregnancy Loss in the First and Second Trimester*. April 30, 2021. Virtual presentation.



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*Making the Connection: Engaging, Empowering, and Sustaining State Advocacy Leaders.* May 17, 2021. ACOG Virtual Presentation.

Rutgers Grand Rounds: *Early Pregnancy Loss Management in the Emergency Department.* July 9, 2021. Virtual Presentation.

UT Austin Grand Rounds: *Early Pregnancy Loss Management in the Emergency Department.* October 21, 2021. Virtual presentation.

University of Washington Grand Rounds: *Medication Management of Abortion and Pregnancy Loss.* March 2, 2022. Virtual presentation

The Center for International Reproductive Health Training (CIRHT) -Kigali Conference: *Establishing a family planning fellowship in the Sub-Saharan Region (or Africa) - the experience of Ethiopia.* Kigali, Rwanda. October 7, 2022.

Annual Deisher Provider Grant Rounds for Seattle Children's Hospital: "*Family Planning for Pediatricians: Practice, Pitfalls, and Allyship*". Seattle, Washington. October 20, 2022.

Society of Family Planning Annual Conference. "Late Breaking News: Mifepristone REMS and Legal Strategy to Protect Mifepristone. Moderator and speaker for Panel Presentation. Baltimore, MD. December 4, 2022.

2023 Washington State of Reform Health Policy Conference. "Reproductive health policies & protections. Panel presentation with Dr. Meghan Eagen-Torkko, ARNP and Leah Rutman, JD. Seattle, WA. January 5, 2023.

31st Annual Conference of Ethiopian Society of Obstetricians and Gynecologists (ESOG). "What's NEXT in contraception?". Addis Ababa, Ethiopia. February 11, 2023.

# Exhibit 16



1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
Civil Rights Division Chief  
5 ANDREW R.W. HUGHES, WSBA #49515  
LAURYN K. FRAAS, WSBA #53238  
6 Assistant Attorneys General  
TERA M. HEINTZ, WSBA #54921  
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10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
BRIAN REED

1 I, Brian Reed, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am the Administrator of Women's and Children's Services at the  
5 University of Washington (UW). In this role, I oversee strategy, planning, and  
6 operations for the provision of women's and children's services across four UW  
7 hospital sites located in the greater Seattle area.

8 3. For the past four months, I have been participating in a work group  
9 at UW that is implementing the amended requirements for the FDA's  
10 mifepristone risk evaluation and mitigation strategy (REMS). This includes the  
11 requirement that mifepristone be dispensed by or under the supervision of a  
12 certified prescriber or by certified pharmacies for prescriptions issued by certified  
13 prescribers. It also requires the use of Prescriber (or Provider) and Patient  
14 Agreement forms. While mifepristone has been subject to a REMS for years, the  
15 latest updated requirements went into effect on January 3, 2023.

16 4. My work on the project for building telehealth medication abortion  
17 services at UW began last summer. Initially, we considered working with third-  
18 party providers to mail mifepristone, but decided instead to set up this process in  
19 house.

20 5. Once we decided to set up an in-house process to mail mifepristone,  
21 we turned to implementation. It has not been an easy process, particularly because  
22

1 ensuring compliance with the REMS has involved developing new technical  
2 processes not required for other drugs.

3 6. Ordinarily, to make an FDA-approved drug available for  
4 prescription by UW providers, we would simply add the drug into a system called  
5 Epic, with no further steps required. For mifepristone, however, because of the  
6 REMS, we have had to create new systems and work-flows to ensure remote  
7 signature of the required forms by patients and prescribers, as well as additional  
8 pharmacy-related work-flows to ensure UW's pharmacies can meet their  
9 verification requirements.

10 7. This work would not exist without the REMS and has created an  
11 additional burden on both providers and staff involved in implementation. There  
12 may be long-term effects of the new REMS program for in-person visits pending  
13 further clarification of the REMS requirement for in-person dispensing. The work  
14 REMS has created has delayed telehealth access to medication abortions by over  
15 two months for patients seeking this care from UW.

16  
17 **The REMS Impose Onerous Requirements on Providers and Raise  
Safety Concerns**

18 8. UW has hundreds of providers who are eligible to provide telehealth  
19 services, but not all of them are able to prescribe mifepristone, in part, due to the  
20 REMS restrictions. To comply with the mifepristone REMS, I am currently  
21 working to determine which UW prescribers are interested in prescribing  
22

1 mifepristone via telehealth. For those providers who are interested, I must then  
2 ensure that they sign a Prescriber Agreement form and submit it to the UW mail  
3 order pharmacy as well as an internal secure database.

4 9. My work currently involves outreach to interested providers, but it  
5 will eventually include training on how to electronically complete the Prescriber  
6 Agreement form for telehealth visits and the additional steps required to submit  
7 the prescription to the UW mail order pharmacy.

8 10. UW is also in the process of creating a secure database (referenced  
9 above) with this information that would allow UW Medicine to check that the  
10 provider has submitted the form and is therefore eligible to write the prescription.  
11 Both UW Medicine and the UW mail order pharmacy will need to be able to  
12 access the database. With that said, I am aware that there is significant concern  
13 about us creating a database of our medication abortion providers due to safety  
14 concerns related to abortion.

15 11. UW is extremely careful in maintaining the safety of our  
16 organization and our providers, particularly in the reproductive healthcare space.  
17 For instance, we have had internal conversations on the pros and cons of allowing  
18 a patient to choose a specific provider for their medication abortion telehealth  
19 appointment, or instead only allowing a patient to request a telehealth medication  
20 abortion appointment at a particular location without selecting a provider. The  
21 latter better protects the identity of our providers who provide medication  
22

1 abortion, but that is not our normal practice and it is technically more difficult to  
2 implement. We have also had to rethink how we design and build our women's  
3 health clinics and whether we should move clinics from the first to the second  
4 floor for safety.

5  
6 **The REMS Unnecessarily Impose Significant Burdens on Patients and  
Create Barriers to Access**

7 12. In addition to the burdens on the providers, the REMS impose  
8 additional burdens on patients. UW has dedicated substantial resources to make  
9 the REMS-required Patient Agreement form available to telemedicine patients.  
10 REMS requires this form to be signed by both the patient and a certified  
11 prescriber before the provider has met their obligation under the Prescriber  
12 Agreement form and the prescription can be filled by the UW mail order  
13 pharmacy. While signing the form is a simple task to complete in person, it poses  
14 significant challenges in the telehealth setting. Previously, we did not have any  
15 system in place to obtain virtual signatures like this.

16 13. Our REMS implementation committee has dedicated significant  
17 efforts to this REMS component, including making the Patient Agreement form  
18 accessible to telemedicine patients in a HIPAA-compliant manner, designing a  
19 method to securely transmit the form to the patient for their signature and then  
20 securely re-route the form back to the provider for their signature, and ensuring  
21  
22

1 timely transmission of the form from the registered provider into the patient's  
2 medical record.

3 14. Additionally, there are significant equity and access issues with  
4 obtaining virtual signatures, as not everyone has access to a printer or scanner.  
5 To attempt to provide equal access, we will be using a form-fillable PDF to be  
6 delivered to the patient during or just after their telehealth abortion appointment.  
7 We had to develop a way to track the patient's signature so that the pharmacy  
8 knew it was completed before dispensing mifepristone. But this process only  
9 works if a person has reliable access to a computer or smartphone and a reliable  
10 Internet connection. This is an entirely new process for our providers and  
11 patients. We are still developing this process and the necessary training, and it is  
12 not fully operational yet.

13 15. There are also patient equity concerns regarding mail order  
14 prescriptions. For our initial rollout of telehealth abortion appointments, we are  
15 planning to require all telehealth patients to have mifepristone dispensed using  
16 UW's mail order pharmacy. This is due to administrative burdens created by the  
17 REMS. While mail order works well for many patients, we are aware that it is  
18 not a good option for individual in rural communities that only have a PO Box  
19 (which we cannot ship medications to). It likewise makes delivery of medication  
20 to people who are unhoused or unstably housed, or who do not have a permanent  
21 physical address a significant challenge.  
22



# Exhibit 17



1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
Civil Rights Division Chief  
5 ANDREW R.W. HUGHES, WSBA #49515  
LAURYN K. FRAAS, WSBA #53238  
6 Assistant Attorneys General  
TERA M. HEINTZ, WSBA #54921  
7 (application for admission forthcoming)  
Deputy Solicitor General  
8 800 Fifth Avenue, Suite 2000  
Seattle, WA 98104-3188  
9 (206) 464-7744

10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
SAMANTHA ROLLAND IN  
SUPPORT OF MOTION FOR  
PRELIMINARY INJUNCTION

1 I, Samantha Rolland, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am the Vital Records Epidemiology Supervisor with the  
5 Washington State Department of Health. I have held this position since  
6 December 2019.

7 3. The Department of Health tracks data related to abortions in  
8 Washington, including the number of abortions, the methods, and rates of  
9 complications. In my role as the Vital Records Epidemiology Supervisor,  
10 I supervise the collection of these data.

11 4. I have bachelor's and master's degrees in microbiology from  
12 Brigham Young University, a Ph.D. in microbiology and molecular genetics from  
13 the University of Vermont, and a Masters of Public Health from Johns Hopkins  
14 University.

15 5. Based on my review of the data DOH collects, I am aware that  
16 mifepristone is commonly used for medication abortions in Washington.

17 6. In 2021 there were 15,358 Washington resident abortions that  
18 occurred in Washington.<sup>1</sup> Of these, 9,060 (59.0%) were medication abortions  
19 \_\_\_\_\_

20 <sup>1</sup>DOH defines residency based on patient's reported state of residence, and  
21 an abortion as having occurred in Washington based on the facility's location  
22 where applicable. In cases of medication abortions where the medication is

1 involving the use of mifepristone. Of these 9,060 mifepristone abortions,  
 2 142 (1.6%) reported complications, with the two most commonly reported  
 3 complications being retained products of conception (52.1%) and a failed  
 4 abortion (45.1%). Fewer than 0.1% of mifepristone abortions in 2021 resulted in  
 5 a complication severe enough to warrant hospitalization.

6 7. In 2020, there were 15,487 Washington resident abortions that  
 7 occurred in Washington. Of these, 8,550 (55.2%) were medication abortions  
 8 involving the use of mifepristone. Of these 8,550 mifepristone abortions,  
 9 175 (2.0%) reported complications, with the two most commonly reported  
 10 complications being retained products of conception (58.3%) and a failed  
 11 abortion (36.0%). Fewer than 0.1% of mifepristone abortions in 2020 resulted in  
 12 a complication severe enough to warrant hospitalization.

13 I declare under penalty of perjury under the laws of the State of  
 14 Washington and the United States of America that the foregoing is true and  
 15 correct.

16 DATED this 14th day of February 2023, at Olympia, Washington.

17 

18 SAMANTHA ROLLAND  
 19 Vital Statistics Epidemiology Supervisor  
 20 Washington Department of Health

21 \_\_\_\_\_  
 22 mail-ordered and there is no physical facility located in Washington, DOH uses  
 the patient's state of residence as the abortion location.

# Exhibit 18

1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
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5 ANDREW R.W. HUGHES, WSBA #49515  
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10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
GRACE SHIH, MD, MAS

1 I, Grace Shih, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am an Associate Professor in the Department of Family Medicine,  
5 with a clinical practice at the University of Washington (UW) Primary Care at  
6 Northgate where I practice family medicine and run the Reproductive Health  
7 clinic. I oversee training UW School of Medicine family medicine residents on  
8 reproductive care. I am also the Director of the Family Medicine Residency  
9 Network, a group of thirty-three family medicine residency programs at different  
10 university medical facilities and family medicine clinics throughout Washington,  
11 Wyoming, Alaska, Montana and Idaho.

12 3. I completed my medical degree at the University of Florida and my  
13 family medicine residency at Brown University. I completed my Family Planning  
14 Fellowship at the University of California, San Francisco. I am also board  
15 certified in family medicine. My CV is attached as Exhibit A. I have published  
16 research on comprehensive family planning including abortion care, particularly  
17 with regards to family medicine training and integration into primary care  
18 services<sup>1</sup>. See Exhibit A for the full list of my published research.

19 \_\_\_\_\_  
20 <sup>1</sup> Witt L.B., Wolff S., Shih G., French V., *Abortion and contraception in*  
21 *medical school curricula: a survey of North American family medicine clinical*  
22 *curriculum directors*, Teach Learn Med,13:1-9 (Jan. 2023); Verma N., Goyal V.,

4. I am submitting this declaration in support of the State of Washington's motion for a preliminary injunction.

**My Patients & My Practice at UW**

5. I treat patients in a family medicine practice at UW. As UW is a teaching institution, I also supervise and train medical residents and students.

6. My areas of clinical interest include family planning and contraception (intrauterine devices and implant contraception placement and

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Grossman D., Peritt J., Shih G., *Society of Family Planning Interim Clinical Recommendations: Self-Managed Abortion, Contraception* (2022); Miles C., Weidner A., Summit A.K., Thomson C.J., Zhang Y., Cole A.M., Shih G., *Patient opinions on sexual and reproductive health services in primary care in rural and urban clinics*, *Contraception* 114:26-31 (Oct. 2022); Wallace R., Shih G., *Complex Family Planning - Demarginalizing abortion care requires uplifting primary care and non-CFP providers*, *Contraception* 105:86, (Jan. 2002); Thomson C.J., Zhang Y., Weidner A., Summit A.K., Miles C., Cole A.M., Shih G., *Patient Concerns about Accessing Sexual and Reproductive Health Services Outside of Primary Care: A Survey in Rural and Urban Settings in the Pacific Northwest*, *Contraception* 15:S0010-7824(22)00396-1 (Oct. 2022); Zhang Y., Sheth S., Weidner, A.K.H., Egwuatu, P., Webb, L., Shih G., *Immediate Postpartum IUD Training Within a Regional Network of Family Medicine Residencies*. *PRiMER* 1;5:24 (July 2021).

1 removal, medication and aspiration abortion, uterine aspiration for miscarriage  
2 management, and vasectomy), reproductive health (fertility counseling,  
3 colposcopy), gender affirming care, women's health, and adolescent medicine.

4 7. As part of my practice, I treat patients who are pregnant, including  
5 those facing unintended pregnancies.

6 8. When I treat such patients, I always begin the patient visit by  
7 establishing rapport and creating a safe environment for open and honest  
8 conversation. I ask patients open-ended questions to determine their desires for  
9 their pregnancy. I ensure that their decision is their own. I review the patient's  
10 medical history, symptoms, and estimate gestational age. When necessary, I  
11 perform a physical exam and/or obtain relevant imaging/labs. For patients  
12 desiring abortion, I counsel them on the kinds of abortion for which they are  
13 eligible. I then discuss with the patient the risks, benefits and alternatives for each  
14 kind of abortion care for which they are eligible and answer any questions they  
15 may have to ensure that they have the information they need to make an informed  
16 decision about their care. If they are eligible for, and choose, a medication  
17 abortion, we proceed with a more detailed conversation on medication abortion,  
18 including a discussion of the medications mifepristone and misoprostol, which  
19 are a part of a two-drug regimen to end early pregnancy.

20 9. In my counseling, I discuss the medication abortion process. I  
21 describe how mifepristone and misoprostol work, the timing on how to take the  
22



1 medications, and the route to take the medications. I review the side effects and  
2 rare complications. I explain that medication abortion with mifepristone and  
3 misoprostol is highly effective. In the rare event it does not work, I let them know  
4 we can provide more medications and/or an aspiration procedure. I review  
5 reasons for which they should contact our office and/or speak with a provider.  
6 Because mifepristone is subject to certain Risk Evaluation and Mitigation  
7 Strategy (REMS) requirements, I also review the Patient Agreement Form with  
8 the patient as part of my counseling. After answering any questions, I ask whether  
9 they consent to a medication abortion, and if they do, I confirm that consent in  
10 their medical record. I then repeat the instructions for how and when to take their  
11 medication, walk them through the follow-up process, explain what they should  
12 do if they experience any of the (very rare) serious complications associated with  
13 mifepristone, and answer any questions they may have.

14 10. As UW is currently only dispensing mifepristone for medication  
15 abortion in person, I then provide the patient with the mifepristone. To comply  
16 with the Risk Evaluation and Mitigation Strategy (REMS) requirements  
17 associated with mifepristone, I then have the patient sign the Patient Agreement  
18 form, and I sign it as well. I give one copy of the form to the patient, along with  
19 the Medication Guide and medication, and I place the copy of the signed Patient  
20 Agreement form in the patient's record. I also record the NDC (National Drug  
21 Code) and lot number for the mifepristone in the patient's record.  
22

1           11. I also give the patient my pager number and/or the clinic number  
2 and let them know that they should call us if they have any concerns. We rarely  
3 receive calls from patients regarding mifepristone, but if we do, they are generally  
4 questions related to pain management or bleeding.

5           12. Among the patients I have treated, I am not aware of any who have  
6 experienced a serious adverse reaction from mifepristone.

7           13. I also prescribe mifepristone, in combination with the drug  
8 misoprostol, to patients who are experiencing a miscarriage. Using this two-drug  
9 regimen to manage miscarriage has been the basic standard of care at UW since  
10 approximately 2019. The patients I treat for miscarriage are required to sign the  
11 same Patient Agreement Form as patients receiving mifepristone for a medication  
12 abortion.

13           14. Because the Patient Agreement Form covers topics that I already  
14 cover with the patient in my routine counseling, the form does not provide the  
15 patient with any information I would not otherwise provide them. Instead, it is an  
16 added burden for myself and my patients. As a provider, it adds one more  
17 checkbox on an already complex visit. At minimum, the form requires extra time  
18 for review. Because the form is generic, if there are special circumstances the  
19 patient and I have already discussed and differ from the form, this takes extra  
20 time for explanation. For example, the form states “I have decided to take  
21 mifepristone and misoprostol to end my pregnancy.” This does not apply to  
22

1 patients experiencing miscarriage and requires extra explanation and may be  
2 confusing and/or traumatic for them to read. There is also the administrative time  
3 to ensure up-to-date forms are being used and signed forms are properly saved.  
4 For the patient, this puts one more piece of paper in their file identifying them as  
5 having used mifepristone. I find this unnecessary paperwork concerning, given  
6 the heightened external risks for some patients seeking mifepristone for abortion  
7 care.

8 **My Work Implementing the Mifepristone REMS**

9  
10 15. In addition to my regular duties, I have been participating in a  
11 workgroup at UW implementing the amended REMS on dispensing  
12 mifepristone, which took effect on January 3, 2023. Implementing the new  
13 REMS has required a great deal of time and effort from numerous stakeholders  
14 across the University.

15 16. I have been involved with UW's implementation of the REMS on  
16 the provider front. This has involved a lot of time and thought as to how best to  
17 implement the REMS in the telehealth space.

18 17. One of the major challenges the REMS has presented is the  
19 difficulty of obtaining a signed Patient Agreement Form in telehealth  
20 appointments. An enormous amount of effort has been spent determining the  
21 most secure way to provide the required Patient Agreement Form to the client in  
22 the telehealth setting in a way that will be accessible to most patients and allow

1 the form to be signed and securely transferred back to UW. Once signed forms  
2 are securely received by UW, the providers must then be notified so the  
3 mifepristone prescription process can be completed. The additional need to  
4 obtain a signed form transforms a telehealth visit from one in which a telehealth  
5 provider can complete a prescription during the visit to one in which a telehealth  
6 provider must be “on hold” until receipt of the signed form is confirmed and then  
7 the prescription may be completed. While some patients may be able to sign the  
8 form quickly, others may face barriers to internet access or other technology  
9 requirements, delaying their ability to complete the required documentation and  
10 subsequently delaying time-sensitive medical care. The FDA currently approves  
11 of mifepristone-misoprostol abortion up to 70 days gestation. The earliest most  
12 people are aware they are pregnant is at the time of missed period or ~30 days  
13 gestation. Once the decision has been made to pursue medication abortion,  
14 delaying the process even by a few days may make them ineligible to select  
15 medication abortion. In general, delays in abortion care incur higher risks for both  
16 medication and procedural abortion care.

17 18. Another obstacle associated with the REMS is the Prescriber  
18 Agreement Form. Specifically, we have to identify all UW providers who may  
19 want to prescribe mifepristone in the telehealth space and ensure that they  
20 complete a Prescriber Agreement form and transmit it to the UW Pharmacy  
21 (which is becoming a certified pharmacy pursuant to the REMS). This is a major  
22

1 hurdle, as UW has hundreds of providers—including medical residents—who  
2 could potentially prescribe mifepristone in the telehealth setting. We are currently  
3 conducting outreach to let providers know that mifepristone for medication  
4 abortion and miscarriage management can now be prescribed in the telehealth  
5 setting and filled at UW pharmacies—but only if the provider has a Prescriber  
6 Agreement form on file with UW pharmacies. It is a significant logistical burden  
7 to identify *who* is interested in becoming a certified provider, connect with that  
8 provider to explain the process, and then follow up to ensure that they have found  
9 the time in their busy schedule to sign the provider form and transmit it to the  
10 UW pharmacy. I anticipate that this requirement will present an ongoing  
11 administrative burden as new residents and other providers join the UW.

12 19. I estimate that I have worked approximately 30 hours on this project  
13 to date, with additional work still to do, including training residents and other  
14 family medicine colleagues on how to use the newly-developed interfaces for the  
15 Patient Agreement Form, attending committee meetings, and coordinating with  
16 committee members regarding various REMS implementation tasks outside of  
17 those meetings.

18 **The REMS Unnecessarily Impose Significant Burdens on Medical**  
19 **Providers' Abortion Care Practice**

20 20. The January 2023 mifepristone REMS continue to discourage  
21 family medicine providers from prescribing mifepristone in their practice.  
22

1           21. First, the simple fact that a REMS exists for mifepristone creates a  
2 major hurdle for getting family medicine doctors to prescribe the drug. Indeed,  
3 in my conversations with family medicine physicians, the mere existence of the  
4 mifepristone REMS creates a mistaken impression among family medicine  
5 doctors—who are generalists—that mifepristone is a dangerous medication. The  
6 REMS leads some providers to erroneously conclude that the drug is either more  
7 dangerous or more complicated to prescribe than it is, leading them to believe  
8 they are not qualified to prescribe it or that its use requires expertise beyond the  
9 scope of their practice. As a result, some family medicine doctors who provide  
10 pregnancy-related care and are otherwise qualified to prescribe mifepristone  
11 choose not to prescribe it.<sup>2</sup>

12 \_\_\_\_\_  
13           <sup>2</sup> In addition to my personal experience speaking to fellow providers, I am  
14 also aware of published studies concluding that the REMS give providers the  
15 mistaken impression that mifepristone is riskier than it is and appropriate only  
16 for specialists to provide. *See* Danielle Calloway, Debra B. Stulberg, and  
17 Elizabeth Janiak, *Mifepristone restrictions and primary care: Breaking the cycle*  
18 *of stigma through a learning collaborative model in the United States*,  
19 *Contraception* 104 (2021) 24-28; Sarah Neill, Alisa B. Goldberg, and Elizabeth  
20 Janiak, *Medication management of early pregnancy loss: the impact of the US*  
21 *Food and Drug Administration Risk Evaluation and Mitigation Strategy*,  
22 *Obstetrics & Gynecology* 139(1) (May 2022).

22. Second, the Prescriber Agreement Form required by the REMS poses additional barriers to getting more family medicine providers to prescribe mifepristone. Because Prescriber Agreement Forms are not typically required for the types of medications prescribed by family medicine doctors, there is often confusion as to why the form is required. For other family medicine doctors, the Prescriber Agreement Form is an administrative headache that generally requires a provider getting clinic buy in to prescribe a medication the provider is otherwise qualified to provide. If a provider has few patients for whom they anticipate prescribing mifepristone, the provider may simply determine that it is not worth the extra work to become certified.<sup>3</sup>

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<sup>3</sup> Razon, N., Wulf, S., Perez, C., McNeil, S., Maldonado, L., Fields, A.B., Carvajal, D., Logan, R., Dehlendorf, C., *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, *Contraception* 109:19-24 (May 2022); Lee, C.M., Johns, S.L., Stulberg, D.B., Allen, R.H., Janiak, E., *Barriers to abortion provision in primary care in New England, 2019-2020: A qualitative study*, *Contraception* 117:39-44 (Jan. 2023); Goodman, S., Shih, G., Hawkins, M., Feierabend, S., Lossy, P., Waxman, N.J., Gold, M., Dehlendorf, C., *A long-term evaluation of a required reproductive health training rotation with opt-out provisions for family medicine residents*, *Fam. Med.* 45(3):180-6 (Mar. 2013).

1           23. Other providers do not want to complete the Prescriber Agreement  
2 Form as they have concerns that by certifying that they are a qualified medication  
3 abortion provider, they could be exposing themselves to harassment or violence  
4 by anti-abortion activists or to potential prosecution by law enforcement in states  
5 where abortion is now illegal. This fear is particularly acute for physicians who  
6 may hold medical licenses in multiple states, including those that have abortion  
7 laws different from Washington. The fact that a provider has to send their  
8 Prescriber Agreement Form to *every* individual certified pharmacy to which it  
9 may send mifepristone prescriptions further compounds this fear.

10           24. I can personally attest that the fear of being publicly identified as an  
11 “abortionist” is real. My name, picture, medical licenses, and business address  
12 (along with a list of “abortion mill[s]”) are listed on the website  
13 “AbortionDocs.org,” which describes itself as “the largest collection of  
14 documents on America’s Abortion Cartel.” The website is a project of the anti-  
15 abortion organization Operation Rescue. A copy of the webpage containing my  
16 picture and professional information is attached as Exhibit B to my declaration.  
17 Having been publicly identified on this website in this way myself, I can certainly  
18 understand why medical providers fear having their identity made known to anti-  
19 abortion activists and being publicly identified as an “abortionist.”

20           25. The Prescriber Agreement Form also presents a significant barrier  
21 to mifepristone use among resident physicians. At UW, we get residents from all  
22



1 over the country—including states where medication abortion is illegal. For a  
2 resident to prescribe mifepristone via telehealth, they too have to complete a  
3 Prescriber Agreement Form. Signing such a form raises many of the same  
4 concerns for residents that it does for providers—e.g., confusion about its  
5 necessity and concerns regarding their safety and the potential legal implications  
6 if they plan to later practice in a state where abortion is illegal. Likewise, they  
7 may be concerned about future employment prospects given the proliferation of  
8 religiously-affiliated and specifically Catholic-run medical institutions, which as  
9 a general rule, are anti-abortion.

10 26. These REMS-related fears may negatively impact the education UW  
11 residents receive. In our family medicine residency training program, we train  
12 everyone in abortion care. But if the REMS leads residents to “opt out” of such  
13 training due to the fear or stigma of being a “certified” medical abortion provider,  
14 future family medicine doctors will be less equipped to serve their patients’  
15 needs.

16 27. Further, the “certified pharmacy” required by the REMS places an  
17 additional administrative workload on the shoulders of already overworked  
18 healthcare providers. The pharmacy certification requirement means that a doctor  
19 cannot simply call-in a mifepristone prescription to the patient’s desired  
20 pharmacy. Instead, the doctor must research available certified pharmacies near  
21 the patient and then send their prescriber agreement form to the pharmacy before  
22

1 sending the patient's prescription. If a prescriber fails to take this step and sends  
 2 the prescription to a pharmacy that is not certified, or neglects to send their  
 3 prescriber agreement form with the prescription, the patient's prescription will  
 4 be delayed. Given the time-sensitive nature of medication abortion, this delay  
 5 could have a significant impact on the patient's ability to have a medication  
 6 abortion.

7 28. The fear of personal, political, and professional consequences for  
 8 providing abortion care ultimately means that fewer providers are trained and  
 9 qualified to provide this necessary medical care in Washington.

10 **The Mifepristone REMS Impedes Patients' Access to Safe and Necessary**  
 11 **Medication Abortions With their Primary Care Physicians**

12 29. There is a growing body of research supporting patients' general  
 13 desire to receive abortion care within the primary care setting.<sup>4</sup> When a patient  
 14

---

15 <sup>4</sup> Miles, C., Weidner, A., Summit, A.K., Thomson, C.J., Zhang, Y., Cole,  
 16 A.M., Shih, G., *Patient opinions on sexual and reproductive health services in*  
 17 *primary care in rural and urban clinics*, *Contraception* 114:26-31 (Oct. 2022);  
 18 Thomson, C.J., Zhang, Y., Weidner, A., Summit, A.K., Miles, C., Cole, A.M.,  
 19 Shih, G., *Patient Concerns about Accessing Sexual and Reproductive Health*  
 20 *Services Outside of Primary Care: A Survey in Rural and Urban Settings in the*  
 21 *Pacific Northwest*, *Contraception* 15:S0010-7824(22)00396-1 (Oct. 2022);  
 22 Hatcher-Lee, M., Cox, C., Shih, G., *If, when, and how to discuss available*

1 has a visit with their primary care physician, the patient is familiar with the clinic,  
 2 knows the front office staff, is in a physical space where they have had trusted  
 3 contact with physicians, and may have more privacy then they may experience  
 4 walking into a specialty clinic. If abortion services are only available outside of  
 5 primary care, patients worry about increased costs, insurance coverage for  
 6 specialty services, and additional wait time for a referral. Thus, there is a  
 7 significant benefit to increasing access to abortion care in primary care practices.  
 8 But the REMS and its continued “certified prescriber” requirement have  
 9 prevented medication abortion from becoming an established part of family  
 10 medicine. This, in turn, means that many patients who would like to receive a  
 11 medication abortion from their primary care physician are unable to.

12 **The 2023 REMS Are Scientifically and Medically Unnecessary**

13 30. There is no objective medical basis for or value to the mifepristone  
 14 REMS program. In fact, mifepristone is on the World Health Organization’s  
 15 (WHO) list of essential medications. This core list includes “minimum medicine  
 16

17  
 18 \_\_\_\_\_  
 19 *abortion services in the primary care setting*, Women & Health, 14:1-12 (Aug.  
 20 2017); Godfrey, E.M., Rubin, S.E., Smith, E.J., Khare, M.M., Gold, M.,  
 21 *Women's preference for receiving abortion in primary care settings*, J. Womens  
 22 Health (Larchmt) 19(3):547-53 (Mar. 2010).

1 needs for a basic health-care system, listing the most efficacious, safe, and cost-  
2 effective medicines for priority conditions.”<sup>5</sup>

3 31. From my experience counseling patients on medication abortion, the  
4 Patient Agreement Form is duplicative of the information contained in the  
5 mifepristone Medication Guide, as well as the informed consent counseling that  
6 providers are already required to provide.

7 32. Having a provider become a “certified” mifepristone prescriber is  
8 also unnecessary and burdensome. Mifepristone is among the safest drugs family  
9 care providers prescribe. It is less dangerous than insulin, warfarin, penicillin,  
10 and most antibiotics. It is even less dangerous than acetaminophen (Tylenol),  
11 which can be purchased over-the-counter without a prescription. Yet  
12 mifepristone is one of the very few drugs that many family medicine providers  
13 might prescribe that is burdened by a REMS. While I am willing to be a  
14 “certified” mifepristone provider, many other providers are not for the reasons I  
15 discuss above. This, in turn, harms patients as the number of “certified” providers  
16 continues to remain limited.

17 33. Removing the REMS for mifepristone would significantly increase  
18 the number of family medicine providers who would be willing to offer  
19 medication abortion care. This opinion is based on my familiarity with the  
20 \_\_\_\_\_

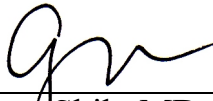
21 <sup>5</sup> World Health Organization, Model List of Essential Medicines, 21<sup>st</sup> Ed.  
22 (2019).

1 literature on this issue, as well as my experience training medical residents over  
2 the last 15 years at UW and University of California, San Francisco. Each year,  
3 when I train residents on medication abortion in clinic, I would estimate that  
4 approximately half of the resident class (usually five residents in a class of 10)  
5 indicate that they are passionate about providing abortion care and hope to  
6 integrate abortion care into their family care practice. However, on average only  
7 about one resident in each class ends up incorporating abortion care (medication  
8 or procedural) into their future primary practice. Some classes have *no* residents  
9 that incorporate abortion into their practices. The low number of residents  
10 ultimately providing medication abortion is attributable in large part to the  
11 barriers imposed by the REMS, including the administrative burden and safety  
12 concerns discussed above.

13 34. Finally, allowing mifepristone to be dispensed only by “certified  
14 pharmacies” serves no value given the highly regulated environment in which  
15 pharmacies already operate. Instead, it harms patients by limiting their ability to  
16 access mifepristone at the pharmacy of their choice, and creates additional  
17 administrative burdens—which I have experienced firsthand in working to  
18 implement the REMS at UW—for both providers and pharmacies, which serve  
19 as additional deterrents to participating in the mifepristone REMS program.  
20  
21  
22

1 I declare under penalty of perjury under the laws of the State of  
2 Washington and the United States of America that the foregoing is true and  
3 correct.

4 DATED this \_\_19\_\_ day of February, 2023, at Anaheim, California.<sup>6</sup>

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7 \_\_\_\_\_  
Grace Shih, MD, MAS

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21 <sup>6</sup> I live and work in Washington, but I am signing this declaration while on  
22 vacation.

# Exhibit A

**Grace Shih, MD MAS**

**PERSONAL DATA**

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Address: 331 NE Thornton Place, Seattle, WA 98125

Email: [ghshih@uw.edu](mailto:ghshih@uw.edu)

Work Phone: (206) 520-2405

Cell Phone: (617) 676-7797

Fax: (206) 520-2450

**EDUCATION**

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1994-1998	Bachelor of Arts Emory University Majors: Music, Physics
1999-2003	Doctor of Medicine University of Florida
2008-2010	Master's Degree in Clinical Research University of California, San Francisco

**POSTGRADUATE TRAINING**

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2004	Internship in Obsetrics and Gynecology Albert Einstein Medical Center
2005-2008	Internship and Residency in Family Medicine Brown University Area of concentration: Maternal and child health
2008-2010	Fellowship in Family Planning University of California, San Francisco
2010-2011	Leadership Training Academy Physicians for Reproductive Health
2014-2015	WWAMI Network Faculty Development Fellowship University of Washington
2017-2018	Certificate Program in Patient Safety and Quality University of Washington
2020	Wiki Scholars Program



## Society of Family Planning

2021-22 STFM CERA Fellowship

FACULTY POSITIONS

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2010-2012	Assistant Clinical Professor Department of Family and Community Medicine University of California, San Francisco
2011-2012	Assistant Clinical Professor Department of Obstetrics, Gynecology and Reproductive Sciences University of California, San Francisco
2013-2014	Acting Assistant Professor Department of Family Medicine University of Washington
2014	Assistant Professor Department of Family Medicine University of Washington
2016-2017	Interim Program Director University of Washington Family Medicine Residency
2018-present	Associate Professor Department of Family Medicine University of Washington
2019-2020	Associate Director, Reproductive Health Advocacy Project (RHAP) Fellowship
2020-present	Co-Director, Reproductive Health Advocacy Project (RHAP) Fellowship Department of Family Medicine University of Washington
2019-2022	Associate Director of Faculty Development WWAMI Family Medicine Residency Network (FMRN) Department of Family Medicine University of Washington
2022-present	Director, WWAMI Family Medicine Residency Network (FMRN) Department of Family Medicine University of Washington

HOSPITAL POSITIONS

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2010-2012	Attending physician Outpatient family medicine and obstetrics San Francisco General Hospital San Francisco, CA
2011-2012	Medical Director New Generation Health Center (Teen family planning clinic) University of California, San Francisco San Francisco, CA
2013-2014	Director, Second Trimester Abortion Services
2021-present	Director, Vasectomy Services Planned Parenthood of the Great Northwest, Hawaii, Alaska, Indiana, and Kentucky Seattle, WA

CURRENT EMPLOYMENT

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See above, N/A

HONORS

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1995	Alexander Means Scholar, four-year full tuition scholarship, Emory University
1995	Barry Goldwater Scholar, scholarship for excellence in science
1996	Hughes Science Scholar, scholarship for excellence in science
1996	<i>Phi Beta Kappa</i> , Emory College
2003	Gold Humanism Honor Society
2003	Caroline Annette Cody Award for dedication to underserved communities, University of Florida School of Medicine
2003	Rotary Cultural Ambassador Scholarship Scholarship to study Spanish and medicine in Quito, Ecuador
2007	Benjamin Josephson Scholar in International Medicine, Brown University
2011, 2012	Excellence in Resident Teaching, Department of Obstetrics Gynecology, UCSF
2013	Full Fellow, Society of Family Planning
2015	MEDEX Golden Apple Teaching Award, UW
2016	Faculty Morale and Support Award, Department of Family Medicine, UW
2015, 2016	Chief Resident Award, Department of Family Medicine, UW
2019	UW Patient Reported Assessment In Doctor Satisfaction and Excellence (PRAISE) Award
2018, 19, 20	Faculty Teaching Award, Department of Family Medicine, UW
2021	HEAR Committee faculty co-lead - Justice, Equity, Diversity, and Inclusion (JEDI) Excellence Award by the UW Department of Family Medicine

2021 Faculty lead, UWNC Northgate Reproductive Clinic Team - Clinical Excellence Award by the UW Department of Family Medicine.

#### BOARD CERTIFICATION

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7/09-present Diplomate, American Board of Family Medicine

#### CURRENT LICENSES

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7/08-present Drug Enforcement Agency

12/12-present Medical license, Medical Board of Washington State

7/18-present Buprenorphine Certificate Waiver

4/20-present NCC Certification of Added Qualification in Electronic Fetal Monitoring

#### DIVERSITY, EQUITY, AND INCLUSION

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##### Committee Membership & Leadership

2014-2018 Member, UW Department of Family Medicine Diversity Committee

2017-present Faculty co-lead, UWFMH Health Equity and Anti-Racism (HEAR) Committee

- Lead race-based caucusing
- Organize and facilitate HEAR curriculum
- Oversee URM Sub-I

2020 Conference Chair, Moving Toward an Anti-Racist Culture of Medicine, WWAMI Network Collaborative Conference. Seattle, WA. September 2020. 300 participants.

2021 Justice, Equity, Diversity, and Inclusion (JEDI) Excellence Award by the UW Department of Family Medicine, HEAR Committee faculty co-lead

2021-present Faculty lead, WWAMI Racial Affinity Caucusing (RAC) Project

##### Scholarship

2009 Understanding Black, Latino, and White couples' attitudes toward sterilization. Fellowship in Family Planning Annual Conference, Chicago, IL. April 2009.

2011 **Shih G**, Vittinghoff E, Steinauer J, Dehlendorf C. Racial and ethnic disparities in contraceptive use in California. Perspect Sex Reprod Health. 2011 September; 43(3): 173-180.

2016 Working toward a more diverse healthcare workforce: Evidence and Strategies. Oral presentation, Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.

2019 **Shih G**, Rind C, Heinen C. All-staff training session to improve transgender sensitivity. Poster presentation, National Transgender Health Summit, San Francisco, CA. April 2019.

- 2020 Ainsworth S, Foster A, Perritt J, **Shih G**, Yanow S. Self-Managed Abortion: Clinical, Activist, and Reproductive Justice Perspectives. National Abortion Federation, Webinar. October 2020.
- 2021 Simon C, Zhang Y, Evans D, **Shih G**, Lindley A, Credit G, Frederickson E, Nelson J. Innovations in Recruitment of URM Applicants during a Pandemic: Creating a Virtual URM Sub-Internship. Virtual Presentation, Annual STFM Conference May 2021.
- 2021 **Shih G**, Lindley AR, Zhang Y, Evans DV. Reaching Out While Staying In: Underrepresented in Medicine Recruitment at the University of Washington Family Medicine Residency. J Grad Med Educ. 2021 Jun;13(3):441.
- 2021 UW CLIME Education Grant, \$5K  
Grant to implement and evaluate racial affinity caucusing for WWAMI residents.

#### Teaching and Mentorship

- 2019 “Reproductive Coercion: History & Current Perspectives,” Residency didactics (~30)
- 2020 Mentored 2 Under-represented in Medicine (URM) Sub-Is by arranging in/outpatient virtual rounding experiences, reviewing/editing application materials, providing mentorship, and connecting each sub-I with other residents/faculty in our program
- 2020 Journal Club: “Racial Inequities in referral for cardiac catheterization” (~30)
- 2021 “Examining Contraceptive Coercion,” Virtual talk for medical students (~50)
- 2020-present STFM Mentor, Mentoring Underrepresented Faculty for Academic Excellence (MUFAE)  
Dr. Odinaka Anyanwu, Brown University FMR Faculty  
Dr. Angela Echiverri, Contra Costa Regional Medical Center FMR Faculty

#### Volunteer Activities & Special Training

- 2019 Faculty co-lead, Doctor for a Day collaboration with Federal Way High School (racially diverse school with <17% white student population) and UWSOM
- 2019 National Coalition Building Institute (NCBI) International Training – Diversity Equity and Inclusion Model Training
- 2020-2022 Steering Committee, People’s Free Telehealth

#### PROFESSIONAL ORGANIZATIONS

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- 2009-present Society of Teachers of Family Medicine
- 2009-present American Academy of Family Physicians
- 2010-present Physicians for Reproductive Health
- 2011-present Society of Family Planning, Full Fellow
- 2014-present Washington Academy of Family Physicians (WAFP)

#### TEACHING RESPONSIBILITIES

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#### Medical and PA Student Education

- 7/09-7/12 UCSF Medical Student Teaching  
Taught 3<sup>rd</sup> and 4<sup>th</sup> year medical students (~50 students/session) in 1-2 lectures/year on women's health topics such as cervical cancer screening, contraception, and abortion care.
- 5/2014 UW MedEx Program  
Taught 1<sup>st</sup> year PA students (~100 students) half-day workshop on contraception.
- 11/17-11/19 UW Medical Students  
Taught 1<sup>st</sup> and 2<sup>nd</sup> year medical students (~10 students/year) 1-2 lectures on human sexuality, family planning, and OBGYN Skills

#### Resident Education

- 7/08-6/12 UCSF Ob-Gyn Residency Teaching  
Provided monthly teaching sessions for Ob-Gyn residents on their family planning rotation (~10 residents/year).
- 7/08-6/12 UCSF Family Medicine Residency Teaching  
I was a Team Lead for family medicine residents (4/year) which included clinical precepting, advising, and mentoring. I also co-led the procedure clinic, provided OB supervision, and didactic teaching. Curricular responsibilities include women's health, family planning, and obstetrics.
- 7/13-present UW Family Medicine Residency Teaching  
I provide education via clinic precepting, hospital service attending, OB attending, seminars, and didactic teaching. My curricular areas of responsibility have included women's health, obstetrics, family planning, transgender care, health equity and anti-racism, advocacy, practice management, and scholarship and research.

#### Fellow Education

- 7/19-present RHAP Fellows and Complex Family Planning (CFP) Fellows  
I provide education for our RHAP fellow (1 UW family medicine fellow, 6 total RHAP fellows nationally) and CFP fellows (2 UW OBGYN fellows) each year on topics including: second trimester abortion, complications in uterine aspiration, cervical preparation, transgender care, vasectomy, ectopic pregnancy, didactic teaching, precepting, and reproductive justice.

#### Faculty Development and Continuing Medical Education

- 2010-11 UCSF Family Planning Faculty Teaching  
I taught 1 lecture/year to the Family Planning division (~10 faculty/year).
- 2014-17 UW Faculty Early Pregnancy Ultrasound Workshop  
Each year, I held a hands-on ultrasound workshop for UW faculty (~5 faculty/year).
- 2016 Advanced Life Support in Obstetrics (ALSO) Course Instructor  
- Shoulder Dystocia  
- First trimester bleeding
- 2018-present WWAMI Hybrid Faculty Development Program (Seattle, WA)  
Each year, I help teach approximately 16 faculty hybrid participants in a year-long fellowship. This program consists of two 2-day in-person sessions and two 2-day

virtual sessions. I provide approximately 4 hours of formal, didactic teaching each year. My curricular responsibility include DEI work, advising and mentoring, and time management.

2018-present WWAMI Faculty Development Fellowship (Seattle, WA)

Each year, I help teach a cohort 12 faculty fellows. I teach approximately 20 hours/year. My curricular responsibility include didactic skills, precepting, advising and mentoring, faculty relationships, career guidance/coaching, cognitive reasoning, time management, and scholarship & research.

#### ADVISING

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2009-2011	Miriam Sheinbein (Planned Parenthood MarMonte Director of Primary Care)
2014	Elizabeth Alcut (UWNC physician)
2014-2015	Ying Zhang (NRSA Fellow, UW Residency faculty)
	Alyce Sutko (Group Health physician, Planned Parenthood physician)
2014-2016	Megan Hatcher-Lee, Medical Student Research Training Program (MSRTP) Advisor (Family Medicine Resident)
2013-2016	Angad Singh (UW Physician lead for eHealth)
	Meena Chelvakumar (Clinical Assistant Professor, Stanford University)
2014-2017	Roshan Najafi (Family physician)
	Michelle Dumond (Fogarty Global Health Fellow)
	Andrea Jochim (Clinical faculty, Harborview Medical Center)
2015-2018	Tara Simpson (UW Global Health Fellow, HealthPoint Residency Faculty)
	Sonali Sheth (UWNC Family physician)
	Lamya Khoury (Family physician)
2015-2018	Patricia Egwuatu (Kaiser Family Medicine Residency Faculty)
2017-2020	Justin Kappel (Clinical faculty, University of Washington)
2019-2020	Jackie Yeh (RHAP Fellow, family physician)
2020-2021	Christie Miles (RHAP Fellow, family physician)
	Aishat Olatunde (UW Complex Family Planning Fellow)
	Monica Agarwal (RHAP Fellow)
2021-2022	Sheila Attaie (RHAP Fellow, family physician)
	CFP Fellow Jennifer Chin (UW Complex Family Planning Fellow)
	Odinaka Anyanwu (Brown University Family Medicine Faculty)
2022-2023	Samantha Glass (RHAP Fellow, family physician)
	Mari Yakimoto (UW Family Medicine Faculty)
	Angela Echiverri (Contra Costa Regional Medical Center Family Medicine Faculty)
	UW FMR PGY3 Natalie Cheung-Jones
	UW FMR PGY2 Amanda Valdes

#### EDITORIAL RESPONSIBILITIES

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2022	Co-Editor, TEACH Early Abortion Training Curriculum, 7 <sup>th</sup> Edition. UCSF Bixy Center for Global Reproductive Health: San Francisco, CA (2022).
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## SPECIAL INTERNATIONAL AND NATIONAL RESPONSIBILITIES

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2014-2019 Board Member, Association of Reproductive Health Professionals (ARHP)  
 2013-2016 Board Member, Training Early Abortion for Comprehensive Healthcare (TEACH)  
 2018-2019 Vice-Chair, Reproductive Health Member Interest Group, AAFP  
 2013-present Co-founder and faculty, Continued Reproductive Education for Advanced Training Efficacy (CREATE)  
 2019-2021 Co-Chair, Reproductive Health Member Interest Group, AAFP  
 2020-2021 Member, National Summit on Family Medicine Residency Education  
 I was invited to participate in a national dialogue on the future of residency training in family medicine hosted by AAFP, ABFM, ACOFP, ADFM, NAPCRG, and STFM.  
 2020-2021 Research Advisory Group, Gynuity International  
 Gynuity International is an organization that focuses on research and policy change to improve reproductive and maternal health outcomes. I was invited to participate in their research advisory group to evaluate clinical protocols and policies on medication abortion.  
 2020-2022 Conference Planning Committee, AAFP Residency Leadership Summit (RLS)  
 2018-present GME Committee Member, STFM  
 2020-present Mentoring Underrepresented Faculty for Academic Excellence (MUFAE), STFM  
 2020-present CERA Survey Peer Reviewer, STFM  
 2020-present Advisory Committee, Midwest Access Project  
 Midwest Access Project is a national nonprofit organization dedicated to offering comprehensive preproductive health training to providers from all disciplines.  
 2022-present CERA Mentor Director, CERA Steering Committee, STFM  
 2023-present Faculty, American College of Obstetrics and Gynecology (ACOG) Implementing Progress in Abortion Care and Training Program  
 I am ACOG faculty that teaching abortion care at residency programs across the nation. Sites: Long Beach Family Medicine Residency Program (2023)

## SPECIAL LOCAL RESPONSIBILITIES

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### Residency Responsibilities

2014-2017 Lead, Scholarship and research UWFMR  
 2015-2017 WWAMI Region Practice & Research Network (WPRN)  
 – UWNC-Northgate research champion  
 2016-2018 Residency recruitment lead, UW Family Medicine Residency  
 2013-present Faculty lead, UWNC-Northgate Reproductive Health Clinic  
 2013-present Faculty mentor, UWFMR Reproductive Health Interest Group  
 2017-present Faculty lead, UWFMR Health Equity and Anti-Racism (HEAR) Committee

### Departmental Responsibilities

2015 Member, UW CME Chair Search Committee  
 2016 Member, UW Associate Program Director Search Committee

2018-2019 Member, UW Department Scholarship Forum Planning Committee  
 2019 Member, UWNC Northgate Clinic Chief Search Committee  
 2019 Member, UWDFM 50<sup>th</sup> Anniversary Planning Committee  
 2017-2021 Member, UW Chairman's Advisory Committee  
 2020-2021 Member, UWDFM 50<sup>th</sup> Awards Selection Committee  
 2015-2023 Member, UW CME Advisory Committee  
 2015-2023 Course Chair, UW Annual Advances in Family Medicine and Primary Care Conference  
 2020-present Member, UWDFM A&P Committee  
 2022-present Member, UWSOM Telemedication Abortion Implementation Task Force

#### External Responsibilities

2018-2022 Reproductive Health Advocacy Project Liaison to AAFP  
 2013-present Selection Committee, UW Fellowship in Family Planning, Department of Ob-Gyn

#### RESEARCH FUNDING AND OTHER GRANTS

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7/09-7/12 Principal Investigator  
 Foundation for Fellowship in Family Planning, \$65K  
*Understanding Black, Latino, and White couples' attitudes toward sterilization*

10/09-7/12 Principal Investigator  
 Foundation for Fellowship in Family Planning, \$30K  
*Knowledge and practice patterns regarding vasectomy among Family PACT providers*

7/10-7/12 Principal Investigator  
 UCSF Reproductive Health Education in Family Medicine (RHEDI) Grant, \$70K  
*Reproductive health training grant*

9/12-7/14 Co-Principal Investigator (UCSF)  
 Hewlett Foundation, \$271K Total  
*Emphasizing characteristics of a long-acting reversible contraception to enhance use*

9/12-7/14 Co-Principal Investigator (UCSF)  
 Hewlett Foundation, \$150K total  
*Making the Copper IUD available for EC: A feasibility and acceptability study*

7/13-7/18 Principal Investigator  
 UW Reproductive Health Education in Family Medicine (RHEDI) Grant, \$70K/year  
*Reproductive health training grant*

3/21-3/22 King County Academy of Family Physicians  
 People's Free Telehealth Grant, \$10K  
*Grant to support the development of free telehealth service for Washington state.*

5/21-5/22 UW CLIME Education Grant, \$5K  
*Grant to implement and evaluate racial affinity caucusing for WWAMI residents.*

#### BIBLIOGRAPHY: PEER REVIEWED JOURNALS

**Shih G** in bold, residents and students in Italics

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1. Magee SR, **Shih G**. Malabsorption of oral antibiotics in pregnancy after gastric bypass surgery. J Am Board of Fam Med. 2007 May-June. 20(3):310-313.
2. Magee S, King W, **Shih G**, et al. Biomonitoring in Rhode Island. Med Health RI. 2008 March. 91(3):88-90.
3. **Shih G**, Njoya M, Lessard M, Labrecque M. Minimizing Pain During Vasectomy: the Mini Needle Anesthetic Technique. J Urol. 2010 May ;183(5): 1959-63.
4. **Shih G**, Turok D, Parker W. Vasectomy: the other (better) form of sterilization. Contraception. 2011 Apr;83(4):310-5
5. Turok D, **Shih G**, Parker W. Reversing the United States sterilization paradox by increasing vasectomy utilization. Contraception. 2011 Apr;83(4):289-290.
6. **Shih G**, Vittinghoff E, Steinauer J, Dehlendorf C. Racial and ethnic disparities in contraceptive use in California. Perspect Sex Reprod Health. 2011 September; 43(3): 173-180.
7. King E, **Shih G**, et al. Mercury, lead, and cadmium in umbilical cord blood. J Environ Health. 2013 Jan-Dec;75(6):38-43.
8. Goodman S, **Shih G**, et al. A long-term evaluation of an opt-out reproductive health training rotation with opt-out provisions for family medicine residents. Fam Med. 2013 Mar; 45(3): 180-6.
9. **Shih G**, Dube K, *Sheinbein M*, Borerro S, Dehlendorf C. "He's a real man": A Qualitative study of the social context of couples' vasectomy decisions among a racially diverse population. Am J Mens Health. 2013 May; 7(3): 206-13.
10. **Shih G**, Dube K, Dehlendorf C. "We never thought of a vasectomy": A Qualitative study of men and women's counseling around sterilization. Contraception. 2013 September; 88(3): 376-381
11. *Nguyen B*, **Shih G**, Turok DK. Putting the man in contraceptive mandate. Contraception. 2014 Jan; 89(1):3-5.
12. Roth M, **Shih G**, et al. Acceptability of a transdermal gel-based male hormonal contraceptive in a randomized controlled trial. Contraception. 2014 Oct; 90(4): 407-12
13. **Shih G**, *Zhang Y*, Bukowski K, Chen A. Bringing men to the table: Sterilization can be for him or for her. Clin Obstet Gynecol. 2014 Dec; 57(4): 731-40
14. **Shih G**, Whited A. When is the best time to clamp the umbilical cord after a routine term vaginal delivery? FPIN HDA: Evidence-Based Practice. 2015; 18(6): 10-11
15. Goodman S, McNeil S, **Shih G**. Simulation for Managing Hemorrhage as a Complication of Uterine Aspiration. MedEdPORTAL Publications; 2015.
16. *Nguyen B*, *Jochim A*, **Shih G**. Offering the full range of contraceptive options: a survey of interest in vasectomy training in the US family planning community. Contraception. 2017 May; 95(5):500-504.
17. Khoury L, **Shih G**. For women of average risk, what are the best tests to screen for Down's Syndrome in the first trimester? FPIN HDA: Evidence-Based Practice. 2017.
18. *Hatcher-Lee M*, Cox C, **Shih G**. If, when, and how to discuss available abortion services in the primary care setting. Women & Health. 2017 Aug 14:1-12.
19. Weidner A, Stevens N, **Shih G**. Associations Between Program-Level Abortion Training and Graduate Preparation for and Provision of Reproductive Care. Fam Med. 2019 Oct;51(9):750-755.

20. **Shih G**, Wu J, Harper D. Awareness and Attitudes Around the New Subspecialty Within Ob/Gyn Called Complex Family Planning: A CERA Survey of Family Medicine Chairs. Fam Med. 2020 Nov;52(10):702-706.
21. Zhang Y, *Sheth S*, Weidner AKH, *Egwuatu P*, *Webb L*, **Shih G**. Immediate Postpartum IUD Training Within a Regional Network of Family Medicine Residencies. PRiMER. 2021 Jul 1;5:24.
22. **Shih G**, Lindley AR, Zhang Y, Evans DV. Reaching Out While Staying In: Underrepresented in Medicine Recruitment at the University of Washington Family Medicine Residency. J Grad Med Educ. 2021 Jun;13(3):441.
23. Wallace R, **Shih G**. Complex Family Planning - Demarginalizing abortion care requires uplifting primary care and non-CFP providers. Contraception. 2022 Jan;105:86. PMID: 34600932.
24. **Shih G**, Stulberg D, Barreto TW, Andrilla CHA, *Guzman S*, Nothnagle M. Faculty and Resident Contraceptive Opt Outs and Training Site Restrictions: A CERA Study. Fam Med. 2022 Feb;54(2):123-128. PMID: 35143684.
25. *Miles C*, *Ennamuri D*, *Yeh J*, **Shih G**. Would you be interested in DMPA-SC? An implementation project in two urban primary care clinics. Contraception. 2022 Aug;112:116-119. PMID: 35123982.
26. *Patel J*, Nguyen BT, **Shih G**, Or M, Harper DM. Vasectomy Training in Family Medicine Residency Programs: A National Survey of Residency Program Directors. Fam Med. 2022 Jun;54(6):438-443. PMID: 35675457.
27. *Miles C*, Weidner A, Summit AK, Thomson CJ, Zhang Y, Cole AM, **Shih G**. Patient opinions on sexual and reproductive health services in primary care in rural and urban clinics. Contraception. 2022 Oct;114:26-31. PMID: 35489391.
28. Thomson CJ, Zhang Y, Weidner A, Summit AK, *Miles C*, Cole AM, **Shih G**. Patient Concerns about Accessing Sexual and Reproductive Health Services Outside of Primary Care: A Survey in Rural and Urban Settings in the Pacific Northwest. Contraception. 2022 Oct 15:S0010-7824(22)00396-1. PMID: 36257376.
29. Verma N, Goyal V, Grossman D, Peritt J, **Shih G**. Society of Family Planning Interim Clinical Recommendations: Self-Managed Abortion. Contraception.
30. Weidner A, Ormsby M, **Shih G**. What's Worth Doing in Virtual Recruitment? A Regional Survey of Program Directors and Incoming Interns. Fam Med. 2022 Nov;54(10):784-790. PMID: 36350743.
31. Witt LB, Wolff S, **Shih G**, French V. Abortion and contraception in medical school curricula: a survey of North American family medicine clinical curriculum directors. Teach Learn Med. 2023 Jan 13:1-9. PMID: 36636862.

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#### BIBLIOGRAPHY: OTHER PEER-REVIEWED SCHOLARLY WORK

1. **Shih G**, Zhang Y, McNeil S. *Continuing Reproductive Education for Advanced Training Efficacy: A Novel Collaborative Program to Support Abortion Practice and Family Planning Advocacy Beyond Residency*. STFM Education Column. July 2018.
2. **Shih G**, Wallace R. *First trimester pregnancy termination: Uterine aspiration*. UpToDate. July 2018, 2020, 2022.

3. **Shih G.** *Abortion by Dilation and Evacuation.* Online Training Module. National Abortion Federation. April 2019.
4. **Shih G,** Wallace R. *First trimester pregnancy termination: Uterine aspiration.* UpToDate. July 2019, 2020.
5. **Shih G.** *No Scalpel Vasectomy.* STFM and AFMRD Family Medicine Residency Curriculum Resource. 2018, 2020, 2022.
6. *Chin J, Ross V, Unger E, Shih G, Zhang Y. Trauma Informed Care for Reproductive Health Services: Fundamentals and Case Discussions.* STFM and AFMRD Family Medicine Residency Curriculum Resource. 2022.
7. Fleming M, **Shih G,** Goodman S and the TEACH Collaborative Working Group. TEACH Abortion Training Curriculum, 7th Edition. UCSF Bixby Center for Global Reproductive Health: San Francisco, CA (2022). Bixby Doc: 2020-001(07/22)

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#### BIBLIOGRAPHY: BOOK CHAPTERS

1. **Shih G.** Chapter: Interstitial Pulmonary Fibrosis. *Ferri's Clinical Advisor.* Mosby Elsevier (2008).
2. Boston Women's Health Book Collective. *Our bodies, ourselves.* New York: Simon & Schuster (2011).
3. Goodman S, Wolfe M, **Shih G,** et al. *Early Abortion Training Workbook, Fourth Edition.* Bixby Center for Global Reproductive Health: San Francisco, CA (2012).

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#### BIBLIOGRAPHY: OTHER PUBLICATIONS

1. **Shih G** (2011). *Life sucks. Or is it just my birth control?*, Bedsider.org (National Campaign to Prevent Teen and Unplanned Pregnancy)
2. **Shih G** (2011). *Consider mother's safety*, USA TODAY, Letter to the Editor
3. **Shih G** (2011). *Where in the world is birth control for men?*, Bedsider.org
4. **Shih G** (2011). *Side effect spotlight: What's up with spotting?*, Bedsider.org
5. **Shih G** (2012). *Does being overweight affect your birth control?*, Bedsider.org
6. **Shih G** (2012). *5 myths about herpes, busted*, Bedsider.org
7. **Shih G** (2013). *Um...Can I get pregnant if?*, Bedsider.org
8. **Shih G** (2014). *Beyond Training: Pearls for Practice*, TEACHtraining.org (Training in Early Abortion for Comprehensive Healthcare)
9. **Shih G** (2014). *Provider Perspectives: Deciding on emergency contraception*, Bedsider.org
10. **Shih G** (2017). *Getting the snip: Should it be me or my partner?*, Bedsider.org
11. **Shih G** (2017). *Birth Control Bullies: When your partner wants your birth control to fail*, Bedsider.org
12. **Shih G** (2017). *5 Vasectomy myths, busted*, Bedsider.org
13. **Shih G** (2021). *How to navigate self-managed abortion issues such as access, wait times, and complications – a family physician explains.* Theconversation.com
14. **Shih G** (2023). *What the FDA's rule changes allowing the abortion pill mifepristone to be dispensed by pharmacies mean in practice – 5 questions answered.* Theconversation.com

MANUSCRIPTS SUBMITTED

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None

ABSTRACTS

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None

PRESENTATIONS: NATIONAL/INTERNATIONAL

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1. **Shih G.** Understanding Black, Latino, and White couples' attitudes toward sterilization. Fellowship in Family Planning Annual Conference, Chicago, IL. April 2009.
2. **Shih G.** Abortion: The Role of Family Medicine. Grand Rounds at Brown University, Pawtucket, RI. April 2010.
3. **Shih G,** Turok D, Parker W, Curington J. No-Scalpel Vasectomy and Occlusion Techniques. Association Reproductive Health Professionals Annual Meeting, Atlanta, GA. September 2010.
4. **Shih G.** Vasectomy: The (other) form of sterilization, Reproductive Health Annual Conference, Portland, OR. March 2012.
5. **Shih G.** New Developments in Contraception. Association Reproductive Health Professionals Annual Meeting, New Orleans, LA. September 2012.
6. **Shih G,** Miller S. Where are the men? Strategies to include men in family planning. Association Reproductive Health Professionals Annual Meeting, New Orleans, LA. September 2012.
7. **Shih G.** Knowledge and practice patterns regarding vasectomy among Family PACT providers. American Public Health Association Annual Meeting, San Francisco, CA. October 2012.
8. **Shih G.** He's a real man: A Qualitative study of the social context of couples' vasectomy decisions among a racially diverse population. American Public Health Association Annual Meeting. San Francisco, CA. October 2012.
9. **Shih G.** Oral Presentation, Association of Reproductive Health Professionals. Webinar, New Developments in Contraception. October 2012.
10. Wallace R, **Shih G.** eLearning for Pregnancy Loss: New Strategies to Teach Miscarriage Management in Family Medicine Settings. Society of Teachers of Family Medicine Annual Meeting. San Antonio, TX. May 2014.
11. Roth M, **Shih G,** Amory J. High Acceptability of a Combination of Nestorone® and Testosterone Gels for Male Hormonal Contraception in a Randomized Controlled Trial (Poster). International Congress of Endocrinology (ICE/ENDO) Annual Meeting. Chicago, IL. June 2014.
12. **Shih G,** Hatcher M, Weidner A. Designing your own qualitative study: A beginner's guide. Society for Teachers of Family Medicine Annual Conference, Orlando, FL. April 2015.

13. Zhang Y, MacNeil S, Castillo P, **Shih G**, Prine L. Teaching advocacy to residents and students: Introducing trainees to health policy through resolution writing. Society for Teachers of Family Medicine Annual Conference, Orlando, FL. April 2015.
14. Castillo P, **Shih G**, Ross V, Overstreet F, Chen F. Working toward a more diverse healthcare workforce: Evidence and Strategies. Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.
15. Wallace R, Prine L, **Shih G**. Pregnancy Loss and Papayas: Use of an innovative video-based curriculum and a hands-on simulation to learn patient-centered miscarriage care in the flipped classroom. Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.
16. **Shih G**, Collins K, Raetz J. Creating scholarly success in residency programs: Evidence & strategies. Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.
17. **Shih G**, Zhang Y, Weidner A. Conducting qualitative data analysis: A basic “how to” seminar. Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.
18. Zhang Y, MacNeil S, **Shih G**. The Strength of the Written Word: Letter-writing as a Powerful Tool for Advocacy and Scholarship. Society of Teachers of Family Medicine Annual Conference, Minneapolis, MN: May 1, 2016.
19. Nguyen B, White K, **Shih G**, Turok D. If sterilization is the question, then vasectomy should be the answer: Increasing the vasectomy workforce. Seminar, North American Forum on Family Planning, Denver, CO. November 2016.
20. Nguyen B, Jochim A, **Shih G**. Vasectomy training in family planning fellowships: Offering the full range of contraceptive options. Poster presentation, North American Forum on Family Planning, Denver, CO. November 2016.
21. Trouton K, **Shih G**, Reeves M, Mark A. Second Trimester Abortions: A Beginner’s Workshop. National Abortion Federation, Seattle, WA. April 2018.
22. **Shih G**. Women’s Health Update. Annual Advances in Family Medicine and Primary Care. Seattle, WA. September 2018.
23. **Shih G**, Rind C, Heinen C. All-staff training session to improve transgender sensitivity. Poster presentation, National Transgender Health Summit, San Francisco, CA. April 2019.
24. **Shih G**, Evans D. Teaching one-minute preceptor with real audio-recordings: A simple, replicable tool for faculty development. Society of Teachers of Family Medicine Annual Conference, Toronto, Canada. May 2019
25. **Shih G**. Self-Managed Abortion: What family medicine physicians need to know. Chat and Chew. Philadelphia, PA. September 2019.
26. **Shih G**, Lindley A, Zhang Y. Intrauterine Procedures: IUDs, EMB, and aspiration. Annual Advances in Family Medicine and Primary Care. Seattle, WA. September 2019.
27. **Shih G**, Ti A. Updates in Contraception: From Emergency Contraception to Permanent Methods. AAFP FMX Annual Conference. Virtual. September 2020.
28. **Shih G**. Updates in Contraception: From Emergency Contraception to Permanent Methods. Annual Advances in Family Medicine and Primary Care. Virtual. September 2020.
29. **Shih G**, panel presentation. Introduction to the Changing Landscape of Medication Abortion. Reproductive Health Access Project, Webinar. October 2020.

30. Ainsworth S, Foster A, Perritt J, **Shih G**, Yanow S. Self-Managed Abortion: Clinical, Activist, and Reproductive Justice Perspectives. National Abortion Federation, Webinar. October 2020.
31. Simon C, Zhang Y, Evans D, **Shih G**, Lindley A, Credit G, Frederickson E, Nelson J. Innovations in Recruitment of URM Applicants during a Pandemic: Creating a Virtual URM Sub-Internship. Virtual Presentation, Annual STFM Conference May 2021.
32. **Shih G**, Lee I, Thompson C. Professional Life Hacks: Making the Most of Your Limited Time. Society of Teachers of Family Medicine Annual Conference. Virtual. May 2021.
33. Lee I, **Shih G**. Defining Your Why and Your What: Using Mission Statements as a Career Compass. Society of Teachers of Family Medicine Annual Conference. Virtual. May 2021.
34. **Shih G**, Lee I. Drawing the line: Identifying and exploring dual relationships between faculty and residents. Society of Teachers of Family Medicine Annual Conference. Live Webinar. May 2021.
35. Graham T, Larson P, Lyon C, **Shih G**, Sokol R, Vasagar B. Faculty for Tomorrow Workshop for Residents. Society of Teachers of Family Medicine Annual Conference. Live Workshop. May 2021.
36. Ormsby M, Weidner A, **Shih G**. Virtual Recruitment: What Do Students Actually Care About? AAFP Residency Leadership Summit Annual Conference. Seminar. March 2022
37. **Shih G**, Lee I. Shifting Ground: Faculty Navigating Multiple Roles with Residents. Seminar. Society of Teachers of Family Medicine Annual Conference. Indianapolis, IN. May 2022.
38. Ormsby M, Weidner A, **Shih G**. Virtual Recruitment: What Do Students Actually Care About? Lecture-Discussion. Society of Teachers of Family Medicine Annual Conference. Indianapolis, IN. May 2022.
39. *Bittner M*, Gold M, *Hutman-Zahler A*, Karlin J, **Shih G**, Bass M. Self-Managed Abortion: Data from an Anonymous Support Hotline. Poster Presentation. Society of Teachers of Family Medicine Annual Conference. Indianapolis, IN. May 2022.
40. Lyon A, **Shih G**, Lawler E, Wallace R. Preparing for the (Criminal) Onslaught: Representing Our Clients in the Wake of Dobbs. National Association for Public Defense Women's Conference. Virtual Seminar. September 2022.

#### PRESENTATIONS: REGIONAL

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1. Godfrey E, **Shih G**. Adolescent Women's Healthcare: Addressing STI's, Contraception & Pregnancy. Washington Association of Family Physicians Annual Meeting, Cle Elum, WA. May 2013.
2. Godfrey E, **Shih G**. Reproductive Sexual Health Using Clinical Cases and Guideline Tools. 41<sup>st</sup> Annual Advances in Family Practice and Primary Care. Seattle, WA. September 2013.
3. **Shih G**, Whited A. FPIN Help Desk Answer: When is the best time to clamp the umbilical cord after a routine term vaginal delivery? WWAMI Faculty Development Fellowship Meeting. Seattle, WA. October 2014.
4. **Shih G**. WWAMI program differences in graduates' reproductive health practices. WWAMI Faculty Development Fellowship Meeting. Seattle, WA. May 2015.
5. WWAMI Chief Resident Conference, Seattle, WA. Annually since May 2015. Topics:
  - Running effective meetings



- Interactive Teaching Strategies
  - Difficult Conversations
  - Precepting
  - Leadership Strategies
6. WWAMI Faculty Development Fellowship, Seattle, WA. Annually since July 2018. Topics:
    - Advising and Mentoring
    - Adult Learning Principles and Applications
    - Precepting
    - Interactive Teaching Tools
    - Tech Tools for Teaching
    - Assessing Clinical Knowledge
    - Individual Learning Plans – Professionalism
    - Individual Learning Plans – Medical Knowledge
    - Professional boundaries
    - Faculty Lift: Understanding the distribution of residency faculty roles
    - Creating an effective research poster
    - Family medicine scholarship overview
    - Time Management
  7. **Shih G**, McGuire M, Stevens N. Managing dual relationships. WWAMI Faculty Development Webinar. Seattle, WA. February 2019.
  8. Miles C, **Shih G**. Patient opinions on sexual and reproductive health services in primary care. WPRN Annual Conference. Seattle, WA. January 2022.
  9. Attaie S, **Shih G**. Shifting landscape of reproductive health. WWAMI Faculty Development Webinar, Virtual. July 2022.
  10. **Shih G**, Ennamuri D, Miles C. Uterine aspiration: Papaya Workshop. WAFP Student and Resident Annual Conference. Olympia, WA. February 2023.

#### PRESENTATIONS: LOCAL

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1. Zhang Y, Castillo P, Sutko A, Chelvakumar M, **Shih G**. Key Articles in Reproductive Health. Continued Reproductive Education for Advanced Training Efficacy (CREATE) Program for Abortion Care - Participants from University of Washington, Kaiser, Swedish-Cherry Hill, and Swedish-First Hill Family Medicine Residency Programs. September 2015.
2. Zhang Y, **Shih G**. Abortion Complications: Uterine Perforation. Continued Reproductive Education for Advanced Training Efficacy (CREATE) Program for Abortion Care - Participants from University of Washington, Kaiser, Swedish-Cherry Hill, and Swedish-First Hill Family Medicine Residency Programs. March 2016.
3. Zhang Y, Sheth S, Khoury L, Sutko A, **Shih G**. Key Articles in Reproductive Health. Continued Reproductive Education for Advanced Training Efficacy (CREATE) Program for Abortion Care - Participants from University of Washington, Kaiser, Swedish-Cherry Hill, and Swedish-First Hill Family Medicine Residency Programs. September 2016.
4. Attaie S, **Shih G**. UW Primary Care Lightning Rounds: Repro Health Update, Virtual. July 2022.

5. Miles C, Thomson C, **Shih G**. Patient preferences and concerns around sexual and reproductive services in primary care. UWDFM Research Seminar. March 2022.

#### SCHOLARLY SERVICE

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2010-present Reviewer, Contraception Journal  
2013-present Manuscript Reviewer, Journal of Women's Health, Issues & Care  
2013-present Manuscript Reviewer, American Journal of Men's Health  
2014-present Manuscript Reviewer, Family Medicine  
2021 Reviewer, Uganda's Coalition for Abortion Telemedicine Handbook to Self Managed Abortion  
2022 Medical expert, KING-5 TV News, Vasectomy  
2022 Medical expert, KIRO-7 TV News, Vasectomy  
2023 Medical expert, KUOW National Public Radio (NPR), Vasectomy

#### COMMUNITY SERVICE

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2010 Shoulder to Shoulder International – Volunteer physician and women's health committee member for non-profit organization committed to health of Intibuca, Honduras.  
2012 No-Scalpel Vasectomy International (NSVI)- Volunteer physician for medical mission to Philippines to teach and provide vasectomies  
2012-present Vasectomy Network – Founder & manager of online community of vasectomy providers (550 members)  
2020-present Miscarriage and Abortion Hotline – Volunteer physician



# Exhibit B

ABORTION  
STATS2023SURGICAL ABORTION CLINICS  
397ABORTION PILL CLINICS  
289ABORTIONISTS  
1465DOCUMENTS  
34376**Grace H. Shih**

Shih, Grace -- pic 1 small

**ABORTION MILL**

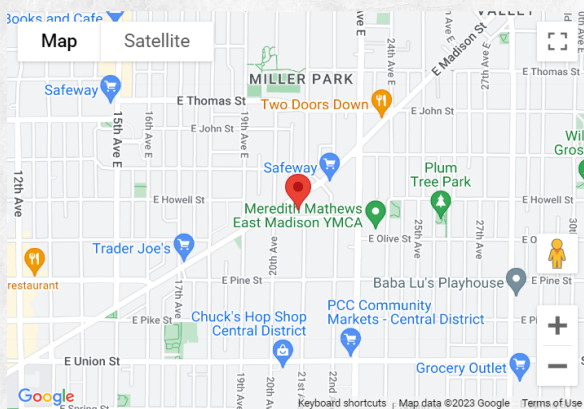
Shelton Health Center-Planned Parenthood  
Seattle Northgate-Planned Parenthood  
Seattle Health Center-Planned Parenthood -- (PP of the Great Northwest and Hawaiian Islands)

**MEDICAL SCHOOL**

University of Florida School of Medicine, 2003

**ADDRESS**

2001 E Madison, Seattle, WA 98122

**PROCEDURES**

Surgery: **YES**  
Medication: **YES**

**OTHER INFO**

Abortionist Grace Shih is an Associate Professor in the Family Medicine Dept at the University of Washington. She completed a Family Planning abortion-training fellowship at UCSF, and helped co-author the "CREATE" abortion-training curriculum. She works at multiple Planned Parenthood abortion clinics.

Former abortionist at: West Seattle Health Center - Planned Parenthood

**PHOTOS****DOCUMENTS****MISC DOCUMENTS****SHIH, GRACE -- 2020 PROVIDENCE DIRECTORY - LISTING AT MANY PP ABORTION CLINICS**

2020 insurance listings at numerous Planned Parenthood abortion clinics, including Shelton, Issaquah, Puyallup, Seattle (Madison St), Federal Way, Marysville, Olympia, Kenmore, Seattle Northgate, West Seattle (now White Center PP), First Hill (Seattle), Bremerton, Centralia, and Kent Valley.

**SHIH, GRACE -- EHEALTHINSURANCE.COM (SCREENSHOT) -- AT THREE PP ABORTION CLINICS**

Listings at West Seattle, Seattle (Madison St), and Northgate Planned Parenthood abortion clinics.

**SHIH, GRACE -- EHEALTHINSURANCE.COM (SCREENSHOT) - LISTING AT SHELTON PP**

Listing at Shelton Planned Parenthood abortion clinic.

**UCSF ABORTION TRAINING MANUAL -- CO-AUTHOR GRACE SHIH**

Abortion curriculum for UCSF, co-authored by Grace Shih, MD. See page 3.

**UW DEPT OF FAMILY MEDICINE -- GRACE SHIH, MD - ABORTION BIO**

Abortionist career info from the UW Dept of Family Medicine.

**UW MEDICINE -- GRACE SHIH, MD, MAS -- ABORTIONS, FAMILY PLANNING FELLOWSHIP AT UCSF**

Shih performs abortions and completed her abortion-training Family Planning Fellowship at UCSF.

**CONTINUING REPRODUCTIVE EDUCATION FOR ADVANCED TRAINING EFFICACY (CREATE) -- ABORTION TRAINING**

"CREATE" abortion training article, co-authored by Grace Shih, MD.

**HEALTH.USNEWS.COM -- DR. GRACE H. SHIH -- AT SEATTLE PP**

Listing at Seattle PP abortion clinic.

**SHIH, GRACE H. -- DOXIMITY.COM -- CREDENTIALS; LISTING AT SEATTLE PP**

Listing at Seattle PP abortion clinic.

**APPLICATION FOR WA STATE LICENSE**

Shih's application for license in WA State

**LICENSE****SHIH, GRACE HONG -- WASHINGTON STATE MEDICAL LICENSE - VALID THROUGH 08-01-2021****SHIH, GRACE HONG -- CALIFORNIA MEDICAL LICENSE - CANCELLED****SUBSCRIBE**

GET THE LATEST NEWS ON ABORTION DOCS

NAME

EMAIL

**SUBMIT**

# Exhibit 19

1 ROBERT W. FERGUSON  
Attorney General  
2 NOAH GUZZO PURCELL, WSBA #43492  
Solicitor General  
3 KRISTIN BENESKI, WSBA #45478  
First Assistant Attorney General  
4 COLLEEN M. MELODY, WSBA #42275  
Civil Rights Division Chief  
5 ANDREW R.W. HUGHES, WSBA #49515  
LAURYN K. FRAAS, WSBA #53238  
6 Assistant Attorneys General  
TERA M. HEINTZ, WSBA #54921  
7 (application for admission forthcoming)  
Deputy Solicitor General  
8 800 Fifth Avenue, Suite 2000  
Seattle, WA 98104-3188  
9 (206) 464-7744

10  
11 **UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND  
16 DRUG ADMINISTRATION, et al.,

17 Defendants.  
18  
19  
20  
21  
22

NO. 1:23-cv-03026

DECLARATION OF  
ANGAD SINGH, M.D.

1 I, Angad Singh, declare as follows:

2 1. I am over the age of 18, am competent to testify as to the matters  
3 herein, and make this declaration based on my personal knowledge.

4 2. I am a board-certified family physician with dual board  
5 certifications in Family Medicine and Clinical Informatics, providing urgent care  
6 services at multiple University of Washington (UW) Medicine Primary Care  
7 locations. I serve as the Associate Chief Medical Information Officer for UW  
8 Medicine with a primary focus on ambulatory care and health equity.

9 Work on the 2023 Mifepristone REMS

10 3. In addition to my regular duties, for the past 6 months, I have  
11 participated operationalizing at UW the FDA's updated risk evaluation and  
12 mitigation strategy (REMS) for mifepristone, which went into effect on January  
13 3, 2023. My work on this project has primarily involved creating and  
14 implementing processes and technological solutions so UW can provide  
15 telemedicine access to medication abortion care in compliance with the 2023  
16 REMS.

17 4. The initial work group was led by Brian Reed, the Administrator of  
18 Women's and Children's Services at UW Medicine. There are approximately  
19 20-25 participants in the work group, in addition to myself.

20 5. The work group started by gaining an understanding of what  
21 currently exists for telehealth abortion care in our health system and identifying  
22

1 what would be needed to build out the process for abortion services consistent  
2 with the 2023 REMS.

3 6. In addition to the work group itself, there are several IT teams  
4 working on building out the workflow for telehealth medication abortions.  
5 Myself and my team coordinate the various elements that must be considered  
6 when constructing a possible workflow for this type of medical visit, including  
7 (1) creation of an appointment and appointment types, (2) development of the  
8 Patient Agreement Form and Prescriber Agreement Forms, (3) creation and  
9 maintenance of a certified prescriber database, (4) integration of automated rules  
10 in the prescription workflow, (5) integration with our electronic health record  
11 (EHR)'s patient portal, (6) management of IT security, patient privacy, and  
12 provider safety concerns, and (7) integration of health equity considerations. We  
13 meet once per week to discuss the necessary technical and workflow  
14 considerations and offer guidance on how systems could be configured. Beyond  
15 the IT team, we have engaged the UW Medicine Digital Health Office and our  
16 electronic health vendor for more nuanced considerations around best practice,  
17 technological possibilities, and impacts on providers and patients.

18 Implementation Challenges Regarding the 2023 Mifepristone REMS

19 7. Because of the unique requirements for prescribing and dispensing  
20 mifepristone under the REMS, making medication abortions available via  
21 telehealth has involved creating an entirely new set of systems and workflows.  
22

1 Operationalizing these new processes has presented a host of challenges for my  
2 team and for other constituent groups at UW. These challenges would not be  
3 present if mifepristone could be prescribed without REMS, like nearly all other  
4 prescribed medications.

5 Patient Appointments for Medication Abortion

6 8. For instance, the process has involved developing a new way for  
7 patients to identify and secure a remote appointment for medication abortion with  
8 a REMS certified provider, including a new appointment type. Since the REMS  
9 requires certain perquisites for a provider to be an eligible prescriber of  
10 mifepristone, limiting an appointment type to a set of medical providers that is  
11 evolving as they gain REMS certification creates both technical and operational  
12 challenges. We have considered and continue to consider whether we have  
13 patients book a generic appointment with a clinic (which could later be changed  
14 to a specific provider), or have a patient select a specific provider at the outset.  
15 While allowing patients to select a specific provider would be the norm in many  
16 other but not all care settings, this is complicated by the above-noted fact that  
17 appointments for a medication abortion can only be made with a certified  
18 prescriber under the mifepristone REMS. We also had to consider the  
19 implications of our technical design on physical safety and assess whether we  
20 could potentially be creating additional safety risks for our providers if a patient  
21 with malicious intent is able to identify a named prescriber by viewing the  
22



1 scheduling portal. On the other hand, masking provider names in favor of generic  
2 appointments raises technical challenges on the back-end to limit scheduling with  
3 only REMS certified providers and makes it more difficult to ensure patient loads  
4 are appropriately divided and that each provider can easily identify their patients  
5 from a pool of generic appointments. These are design trade-offs not normally  
6 considered in establishing a routine telehealth appointment.

7 9. Further, in building-out the appointment process, we considered the  
8 various mechanisms a patient might use to schedule a telehealth appointment. For  
9 the time of the appointment itself, we also considered whether to share a link to  
10 join the appointment for this type of visit via an embedded link in the patient  
11 portal for those who have an account, or via text message or email for those who  
12 do not. In making these determinations, we were mindful that some of our  
13 patients may have ready access to certain telehealth technologies while others do  
14 not, including but not limited to those with financial strain, those who lack  
15 knowledge or comfort with using video conferencing tools, or those in rural areas  
16 that do not have the same broadband access as other parts of the state. These  
17 issues were significant considerations for us in our team's effort to establish  
18 equitable access to medication abortion care.

19 Patient and Prescriber Agreement Forms for Mifepristone REMS

20 10. With the recent amendments to the REMS, we also had to consider  
21 how the Patient Agreement and Prescriber Agreement Forms should be  
22



1 integrated electronically into the larger telehealth workflow. This required  
2 considerable time and effort. Among other things, we had to create a new system  
3 to generate and transmit the Patient Agreement Form to the patient for their  
4 signature; determine how to securely re-route the form back to the provider for  
5 their signature; and then determine how to ensure transmission of the form from  
6 the registered provider to the certified UW pharmacy for storage and reference.

7 11. Given the time-sensitive nature of abortion care, we were keen on  
8 creating a prompt, reliable system for the patient and provider to complete the  
9 REMS-required Patient Agreement Form. We have considered creating built-in  
10 reminders, expiration dates, and other solutions to ensure compliance and prevent  
11 the process from stalling if, for example, a form or signature-reminder message  
12 is inadvertently deleted or fails to deliver to a patient. Such automatic  
13 mechanisms are critical in light of the REMS requirement for a signed Patient  
14 Agreement Form but each represents another technically-challenging, time-  
15 intensive and multidisciplinary process that requires careful consideration to  
16 ensure it is not creating a severe workflow burden.

#### 17 Pharmacy Verification Requirements

18 12. Additional steps also had to be added to the workflow to comply  
19 with the new REMS verification requirements for certified pharmacies. For  
20 instance, before dispensing a prescription, a pharmacy needs to verify that the  
21 prescriber is certified in the Mifepristone REMS Program by confirming that  
22

1 their Prescriber Agreement Form was received with the prescription or is on file  
2 with the pharmacy. We are navigating the technical challenges of maintaining a  
3 secure, reliable, dynamic list of certified prescribers within the hospital's system.  
4 While we recognize that creating a list of certified medication abortion providers  
5 can create additional risk for those providers, such a list is necessary in order to  
6 ensure compliance with the REMS requirements. If any automated hard stops  
7 are required to be built into the electronic health record (EHR), we would need  
8 to create an additional database of certified providers that could be used as a  
9 reference in the EHR. In this case, ensuring that these two databases, which will  
10 necessarily be hosted on separate systems, are always in-sync is a difficult, but  
11 critical issue we have had to address to follow the requirements outlined by  
12 REMS for mifepristone.

13 13. Beyond the technical design considerations to reference certified  
14 REMS providers at UW, we are considering the operational impacts that this  
15 could have. For example, every time a provider is newly certified to prescribe  
16 mifepristone (or if a provider's qualifications lapse or a provider leaves UW), a  
17 technical analyst would need to manually update the EHR list via a help desk  
18 ticket and/or a member of the pharmacy team would separately need to update  
19 the pharmacist-facing list to match. This is a labor-intensive process, creates a  
20 lag time for a mifepristone prescription to be filled, and introduces the risk of  
21 human error with transcription.  
22

1           14. At each phase of this workflow, we also have been considering flags  
2 or other controls that might need to be created to ensure that mifepristone cannot  
3 be prescribed or dispensed until each REMS step has been completed. While  
4 such automatic rules built into the EHR would potentially reduce the risk of  
5 noncompliance, they would also increase the risk of a technical error stalling a  
6 patient's access to mifepristone and required the increased effort of ongoing  
7 maintenance.

8 Safety and Data Security Concerns

9           15. We are continually discussing potential weak points in the new  
10 workflow, in terms of sensitive patient and provider data and overall care  
11 experience.

12           16. The Patient Agreement Form, for example, creates one more  
13 sensitive document with identifying information in a patient's file that must be  
14 appropriately protected.

15           17. We have also had to determine how to securely share the digital  
16 Patient Agreement Form and the link to join the telehealth appointment. Given  
17 the sensitivities associated with medication abortion, we are taking added  
18 technological and training precautions to reduce the risk that any digital tools or  
19 reminders related to the Patient Agreement Form or telemedicine link could not  
20 be inadvertently accessed by someone whom the patient does not wish to have  
21 access, such as a minor patient's parent. But building in these privacy safeguards  
22

1 also creates additional risk that a patient might not receive the reminder, which  
2 would slow down access and require additional provider work and add patient  
3 burden.

4 Training

5 18. Beyond building the systems required to operationalize REMS-  
6 compliant telemedicine abortions, looking forward, UW will need to devote  
7 substantial resources to training each touchpoint on the new processes. Trainings  
8 will need to be created for staff involved in appointing, for providers, for  
9 pharmacists, and for those in medical records. IT will also need to be prepared  
10 to assist on the various systems and practice sessions will need to be run before  
11 the go-live date to troubleshoot any unforeseen issues.

12 Burden of Complying with the 2023 Mifepristone REMS

13 19. All told, I anticipate that the process of implementing telemedicine  
14 abortion care compliant with the 2023 REMS will take at least 10 months. On the  
15 IT side, we started our work in September 2022 (in anticipation of the 2023  
16 REMS) and expect to have the technical components ready by April 2023, with  
17 additional follow-up and training work lasting until approximately June 2023.

18 20. Specifically on the IT side, there are approximately 10 individuals  
19 representing both physician informaticists and technical analysts who are  
20 contributing to the work effort in addition to approximately two staff members  
21 from our EHR vendor who have provided consultative support on the technical  
22

1 considerations of implementing electronic consents. To date, I estimate that UW  
2 personnel on my IT team have spent approximately 150 hours implementing the  
3 mifepristone REMS, and will be expending an estimated additional 150 hours as  
4 we continue to finalize workflow considerations, design training material, and  
5 roll out the initiative.

6 21. Without the REMS in place for mifepristone, prescription and  
7 distribution of mifepristone via telehealth appointments would be routine and  
8 would not require the many hours and resources that have been and will be  
9 devoted to operationalizing this process. This is valuable time that UW  
10 employees could otherwise spend treating patients, teaching clinical medicine,  
11 conducting research, or attending to other critical job functions.

12 22. In my professional opinion, as both a practicing board-certified  
13 family physician and a board-certified physician informaticist, I do not believe  
14 the mifepristone REMS requirements are reducing medical risk, but instead  
15 create significant administrative barriers for hospital systems, providers, and  
16 pharmacies. These barriers, in turn, will make it harder for patients to access  
17 mifepristone.

1 I declare under penalty of perjury under the laws of the State of  
2 Washington and the United States of America that the foregoing is true and  
3 correct.

4 DATED this 21st day of February, 2023, at Seattle, Washington.

5 

6 

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Angad Singh, MD